Title 15 - Mississippi State Department of Health

Part II – Epidemiology

Subpart 11 –Office of Communicable Diseases

CHAPTER 01 RULES AND REGULATIONS GOVERNING REPORTABLE DISEASE AND CONDITIONS

PREFACE

AUTHORITY FOR THE MISSISSIPPI STATE BOARD OF HEALTH TO MAKE AND PUBLISH RULES AND REGULATIONS

Section 41-3-17, Mississippi Code of 1972 as amended

"The State Board of Health is authorized to make and publish all reasonable rules and regulations necessary to enable it to discharge its duties and powers and carry out the purposes and objectives of its creation, and reasonable sanitary rules and regulations, to be enforced in the several counties by the county health officer under the supervision and control of the State Board of Health."

DEPARTMENT TO ESTABLISH AND MAINTAIN A CENTRAL CANCER REGISTRY

Section 41-91-5, Mississippi Code of 1972 as amended

- 1. "The department may establish and maintain a central cancer registry for the state.
- 2. The cancer registry shall be a central data bank of accurate, precise and current information that medical authorities agree serves as an invaluable tool in the early recognition, prevention, cure, and control of cancer."

Section 41-91-7, Mississippi Code of 1972 as amended

- 1. The board may adopt rules and regulations that the board considers necessary to implement this chapter.
- 2. The board in its rules and regulations shall specify the types of information to be provided to the cancer registry and the persons and entities who are required to provide such information to the cancer registry.
- 3. The Department may:
 - a. Execute contracts that the department considers necessary;
 - b. Receive the data from medical records of cases of cancer that are in the custody or under the control of clinical laboratories, hospitals, physician(s) offices and cancer treatment centers or other health care providers to record and analyze the data related to those diseases:

PENALTY FOR VIOLATING RULES AND REGULATIONS OF THE MISSISSIPPI STATE BOARD OF HEALTH

Section 41-3-59, Mississippi Code of 1972 as amended

"Any person who shall knowingly violate any of the provisions of this chapter, or any rules or regulations of the State Board of Health, or any order or regulation of the Board of Supervisors of any county herein authorized to be made, shall be guilty of a misdemeanor, and on conviction shall be punished by a fine not exceeding five hundred dollars or imprisoned in the county jail not more than six months, or both."

MISSISSIPPI STATE DEPARTMENT OF HEALTH RULES AND REGULATIONS GOVERNING REPORTABLE DISEASES AND CONDITIONS.

100 **DUTY TO REPORT**

Each clinician including each physician, pathologist, nurse practitioner, medical examiner; and coroner, laboratory director and veterinarian, in epizootic diseases, shall report to the Department of Health any diagnosed case or suspected case of a reportable disease or condition, including those hereinafter listed, which he or she is attending, has examined, or of which he or she has knowledge. Reports on patients originating from institutions (including but not limited to hospitals and nursing homes) may be coordinated through a designated person, such as an infection control practitioner, provided there is prior arrangement with the Mississippi State Department of Health, Epidemiology Program. Such report shall include, unless otherwise specified, the patient's name, address, age and/or date of birth, race, sex, the disease or suspected disease or condition, the date of onset of the disease, method of diagnosis, and name of attending clinician.

All Class 4 reports should be submitted to:

Mississippi Cancer Registry Cancer Research and Registries University of Mississippi Medical Center 2500 North State Street Jackson, MS 39216 Phone: 601-815-5482

Fax: 601-815-5483

All reports so made are confidential. Reports shall be made as required for each class. Case Report Cards for written reports are supplied through the local health department. When a report to the local health department is made by telephone or in person, the local health officer or his or her designee shall be responsible for preparing the Case Report Card, and forwarding it to the Epidemiology Program.

The designated diseases and conditions listed in Appendix A to the <u>Rules and Regulations Governing Reportable Diseases and Conditions</u> shall be reported using the following classifications. The list designating the reportable diseases and conditions shall be published annually in the <u>Mississippi Morbidity Report</u> and is also available upon request to the Epidemiology Program.

100.01 **Definitions.**

- 1. Class 1: Diseases of major public health importance which shall be reported directly to the Department of Health by telephone within 24 hours of first knowledge or suspicion. Class 1 diseases and conditions are dictated by requiring an immediate public health response. Laboratory directors have an obligation to report laboratory findings for selected diseases (Refer to Appendix B to the Rules and Regulations Governing Reportable Diseases and Conditions).
- 2. Class 2: Diseases or conditions of public health importance of which individual cases shall be reported by mail, telephone or electronically, within 1 week of diagnosis. In outbreaks or other unusual circumstances they shall be reported the same as Class 1. Class 2 diseases and conditions are those for which an immediate public health response is not needed for individual cases. Laboratory directors have an obligation to report laboratory findings for selected diseases (Refer to Appendix B to the Rules and Regulations Governing Reportable Diseases and Conditions.
- 3. Class 3: Laboratory based surveillance. Reported by laboratory only. Diseases or conditions of public health importance of which individual laboratory findings shall be reported by mail, telephone, or electronically within one week of completion of laboratory test (refer to Appendix B of the Rules and Regulations Governing Reportable Diseases and Conditions.). Types of results deemed reportable may be updated due to changes in technology by the State Epidemiologist upon advice of the Director of the Public Health Laboratory.
- 4. **Class 4**: Diseases of public health importance for which immediate reporting is not necessary for surveillance or control efforts. Diseases and conditions in this category shall be reported to the Mississippi Cancer Registry within 6 months of the date of first contact for the reportable condition.
- State Epidemiologist; with the concurrence of the State Health Officer, when the Board is not in session, may declare a disease or condition reportable for a specific length of time, not to exceed 12 months. The Board shall be informed of any action taken under this provision at its next regular meeting. The intent and purpose of this authority is to allow rapid investigation of and response to new or emerging threats to the health of the public.

101 CASE DEFINITIONS

For reporting purposes, the criteria for diagnosis of reportable conditions shall be those specified by the Council of State and Territorial Epidemiologists and the Centers for Disease Control and Prevention, , as outlined in the surveillance case definitions contained in Appendix C to the <u>Rules and Regulations Governing Reportable Diseases</u> and Conditions.

102 DUTY OF LABORATORY DIRECTORS TO REPORT

It shall be the duty of the director or other person in charge of any clinical laboratory in the State of Mississippi or serving Mississippi clinicians or institutions to notify the Mississippi State Department of Health of any laboratory finding as provided for in Appendix A of the Rules and Regulations Governing Reportable Diseases and Conditions for all classes of diseases or conditions. The report shall in all cases include the name and location of the physician or other health care provider ordering the test in addition to the patient identifying information specified in Section 100. Tests considered reportable shall be those listed in Appendix B to the Rules and Regulations Governing Reportable Diseases and Conditions.

103 DUTIES OF LOCAL HEALTH OFFICER

The director of the local health department, as the local health officer, shall be responsible for the control of communicable diseases and other conditions within his or her jurisdiction considered prejudicial to the public health. It shall be his or her duty to collect and make reports as required to the Mississippi State Department of Health, to provide consultation services to physicians regarding communicable diseases, to advise and consult with all others in matters relating to public health, and to investigate reports of known or suspected communicable diseases or of conditions which might be prejudicial to the public health. It shall be his or her duty to determine in individual cases or groups of cases whether to impose restrictions on the activities of patients or contacts of persons with a communicable disease and to fix the period of isolation for such diseases. For all the diseases listed in Appendix A, Class 1 the local health officer shall, on first knowledge or suspicion, conduct an investigation into all the circumstances and prescribe such reasonable methods of control as may be calculated to minimize the danger of further dissemination of the disease process. The measures proposed in the most current edition of the Control of Communicable Diseases Manual, published by the American Public Health Association shall be considered as supplementary. In all matters where there is disagreement as to diagnosis, isolation or in any other situation where the responsibility rests with the health officer, the opinion of the health officer shall prevail. In the discharge of his or her duties, the health officer or designee shall not be denied the right of entry to any premises nor shall he or she be denied pertinent patient health information and patient identifiers.

104 REPORTING OF PATIENTS WHO ABANDON TREATMENT

If any patient suffering from any of the diseases or conditions listed in Appendix A to the Rules and Regulations Governing Reportable Diseases and Conditions leaves the care of his/her physician or leaves any hospital, and the condition of the patient is considered harmful to the public health, it shall be the duty of the attending physician or superintendent or other person in charge of the hospital to report the circumstances to the Department of Health, whether the case has been previously reported or not.

105 SUSPECTS OR CONTACTS OF COMMUNICABLE DISEASES REQUIRED TO SUBMIT TO EXAMINATION

The local health officer is authorized to examine, treat, and/or isolate at his or her discretion or under the direction of the State Health Officer any person who, on credible information, is suspected of suffering from any communicable disease, or who is a contact with a known case of such disease or may be a carrier or have the disease in the incubation or prodromal phase. Said suspect or contact shall be notified in writing to report to a reasonable place at a reasonable time for such examination. Should the suspect or contact refuse to submit to examination satisfactory to the health officer, said suspect or contact shall be prosecuted at law to compel compliance and/or be isolated in a manner prescribed by the health officer until the danger of transmitting the disease in question has passed. In the event that the aforementioned suspect or contact is a minor, the parent or guardian shall be apprised of the facts and requested to deliver said minor for examination. In the event of refusal, the health officer shall maintain action at law to compel compliance of the parent or guardian and/or impose isolation as necessary.

106 PERSONS IN CHARGE OF CERTAIN BUSINESSES AND INSTITUTIONS REQUIRED TO EXCLUDE CERTAIN PERSONS

When any superintendent or other person in charge of any school or other institution, whether public or private, or the person in charge of any establishment or business dealing with perishable foods or foodstuffs for public consumption knows or suspects that any person attending or employed in said school, institution, or business is afflicted with any disease transmissible under the conditions prevailing in that institution or establishment, said person in charge shall exclude the affected person from attending or working in said school, institution or business until he/she shall have been declared by the health officer, or by medical certification acceptable to the health officer, not to be a significant threat to the health of others as a result of the above mentioned disease.

107 FOOD HANDLING ESTABLISHMENTS

The production, processing, storage, handling, distribution and sale of food for human consumption shall conform to the specifications of the current Mississippi Food Code. Local authorities may impose additional, specific requirements. It shall be the duty of the local health officer to investigate any potential or actual disease occurrence in connection with food handling and to impose any measures he/she deems necessary for its control.

108 NOTIFICATION OF OTHER HEALTH CARE PROVIDERS

Any provider of health care services, including but not limited to physician, hospital, and emergency clinic who refers or transfers a patient to another provider of health care services and who has knowledge that the patient has one of the conditions listed in Section 112 or carries the infectious agent thereof or any other disease or agent transmissible under the circumstances of the care to be provided, shall advise the health care service provider to whom the patient is referred or transferred of the presence of the condition together with pertinent details as indicated by accepted standards of medical practice.

109 NOTIFICATION OF THIRD PARTY INDIVIDUALS

In certain circumstances where such notification has significant potential for interrupting the transmission of disease, the Department of Health, through its official representatives, may notify a third party of the presence of a reportable disease in another person. Such notification shall be subject to the prior approval of the State Health Officer or of the State Epidemiologist, and shall take place only under the following conditions:

- Significant, medically recognized, and biologically plausible potential for the transmission of the disease involved must exist under the circumstances;
- 109.02 The party to be notified:
 - 1. Must be at significant risk of acquiring the disease in question or of aggravation of the disease by additional exposure if such notification does not occur, and be potentially able to avoid such transmission by realistic means as a result of the notification; or,
 - 2. Must stand in *loco parentis* or otherwise be responsible for the activities of other persons whose activities could realistically be expected to produce the potential for transmission of the disease to other individuals, and such notification would enable that person to take action which could realistically result in prevention of transmission; or,
 - 3. Could, with such notification, aid in preventing further transmission of the disease by offering testimony in a judicial proceeding concerning the infected individual's violation of an order of the Mississippi State Department of Health.
- 109.03 Such notification shall always be dependent on the presence of a disease that can be transmitted under the circumstances involved, and where there either is no other practical means of limiting transmission or where notification provides such a significant advantage over other means of attempting to reduce transmission that in the opinion of the State Health Officer or the State Epidemiologist, notification is warranted.

110 NOTIFICATION OF EMERGENCY MEDICAL SERVICE PROVIDERS - POSTEXPOSURE

When in the course of providing emergency services to an individual, an emergency medical technician, firefighter, peace officer, or other provider of emergency services comes into direct bare-skin contact with the patient's blood or other internal body fluids, and the patient is transported to a medical care facility, the emergency medical services provider shall notify the medical facility of the blood exposure. Notification shall be in writing and shall include the date and time of the exposure, a description of the nature of the exposure, and the circumstances under which it occurred. If the medical facility to whom the victim is delivered learns during that admission or episode of treatment that the patient has one of the conditions listed in Section 112 or carries the causative agent thereof, the medical facility shall then advise the emergency medical service worker who was exposed as to the condition which was present, and the need for any protective measures to be taken. The hospital shall retain in the patient's medical record a copy of the written notification by the emergency medical services provider of the exposure. The emergency service provider and/or the agency to which he or she is employed shall not disclose any patient identifying information provided under this section to any other person or agency.

PREVENTION OF BLOODBORNE PATHOGENS DURING EXPOSURE-PRONE PROCEDURES

The Guidelines for Prevention of Transmission of Human Immunodeficiency Virus and Hepatitis B Virus to Patients during Exposure-Prone Invasive Procedures published in the MMWR by the Centers for Disease Control and Prevention shall be the guidelines followed in all applicable circumstances in the State of Mississippi. (Copies of these guidelines may be obtained by contacting the Epidemiology Program at 601-576-7725.) This document may also be accessed at www.cdc.gov/mmwr/preview/mmwrhtml/00014845.htm.

112 BLOODBORNE AGENTS

The State Board of Health declares the following diseases and/or infectious agents, transmissible by blood or body fluids, to require the use of appropriate blood and body fluid precautions, including notification of other health care personnel, emergency medical personnel, and providers of post-mortem services as indicated by accepted standard of medical practice or required by law.

Transmissible by Blood or Body Fluids

Creutzfeldt-Jakob Disease Human Immunodeficiency (CJD) Virus (HIV) infection

Hepatitis B Syphilis

Hepatitis C Viral Hemorrhagic Fever

113 TESTING FOR HUMAN IMMUNODEFICIENCY VIRUS INFECTION

Testing for infection with human immunodeficiency virus (HIV) shall be performed only under the following conditions:

- 113.01 No individual or agency shall perform screening tests or collect specimens for the performance of such tests without either the ability to perform appropriate confirmatory tests, such as fluorescent antibody, Western blot, or other tests accepted as confirmatory by the State Department of Health, or arrangements to have such confirmatory tests performed.
- 113.02 Individuals tested for HIV infection shall be notified of the results of the testing only upon completion of appropriate confirmatory or second level test such as fluorescent antibody, Western blot, or other tests accepted as confirmatory by the State Department of Health.
- 113.03 No testing shall be performed without appropriate post-test counseling of individuals tested.
- All conditions stated above pertain to any brand of rapid HIV test. Exceptions:

 1) "negative" rapid HIV test results may be provided directly to the patient. 2) provision of "preliminary positive" rapid HIV test results to the patient pending receipt of required confirmatory test results is permitted. Providers offering rapid HIV testing should receive specific pre- and post-test counseling training. It is preferred that the confirmatory test specimen collection occur immediately, but if that is not possible, every effort should be made to assure that the patient reports for confirmatory testing as soon as possible.

114 IMPORTATION OF WILD ANIMALS

Any wild animal (including but not limited to raccoons, skunks, foxes, prairie dogs and ferrets) known to be capable of harboring and transmitting any disease which may affect humans (such as rabies), or of harboring the vector which transmits the illness (such as plague), from an area or farm enzootic for that illness, shall not be imported into the state

115 Storage of Biologicals

All local health offices, pharmacies, drug stores, apothecary shops, wholesale drug houses and other entities or institutions located within the State of Mississippi and selling or offering to sell or furnish to the public certain biologicals to be used for the purpose of preventing or curing disease shall maintain refrigeration systems in which said biologicals shall be stored at all times. The temperature of the refrigeration system shall not be above 46° F at any time. In the compartment of the refrigeration system where biologicals are stored, a standard thermometer shall be so placed in a fixed position as to indicate the average temperature of the storage compartment. Except for oral polio vaccine, varicella vaccine and other biologicals which must remain frozen until time of use, products should not be placed against ice or stored and maintained at temperatures below 35° F.

116 Specific Disease Control Measures

The following measures shall be used to control or prevent the included diseases of public health importance. The measures proposed in the most current edition of the Control of Communicable Diseases Manual, published by the American Public Health Association shall be considered as supplementary.

116.01 Anthrax

1. Class 1 case report required.

2. Human infections:

Any person infected with anthrax shall be isolated until all lesions are healed or the diagnosis disproved to the satisfaction of the health officer. All lesion discharges shall be subjected to concurrent disinfection in a manner acceptable to the health officer.

116.02 Brucellosis (Undulant Fever)

- 1. Class 2 case report required.
- 2. Whenever the local health officer shall have reason to suspect that any dairy herd may be infected with brucellosis he/she shall prohibit the movement, sale or giving of milk from the herd until the herd is proven free of brucellosis by veterinary certification acceptable to him/her. Milk shall be from dairy herds under a brucellosis eradication program complying with requirements set forth in the current Mississippi State Board of Health Regulations, and the Mississippi State Department of Health's Regulations Governing the Production and Sale of Milk and Milk Products.

116.03 Cancer

- 1. Class 4 case report required.
- 2. Diseases and conditions in this category shall be reported within six months of the first date of contact for the reportable condition to the Mississippi Cancer Registry. The National Program of Cancer Registries at the Centers for Disease Control and Prevention requires the reporting of certain diseases and conditions. A comprehensive reportable list including ICD9CM codes is available on the Mississippi Cancer Registry website, http://mcr.umc.edu/documents/Reportablecasesafter1006.pdf
- 3. Each record shall provide a minimum set of data items which meets the uniform standards required by the National Program of Cancer Registries at the Centers for Disease Control and Prevention and documented in the North American Association of Central Cancer Registries (NAACCR), *Standards for Cancer Registries, Volume II.* [Refer to Section 41-91-7(2) (b), Mississippi Code 1972 as amended. See Preface.]

116.04 Diphtheria

- 1. Class 1 case report required.
 - a. Every case or suspected case of diphtheria shall be isolated until 2 cultures from the throat and 2 from the nose taken not less than 24 hours apart and not less than 24 hours after antibiotic therapy fail to show diphtheria bacilli. Where culturing is impractical, isolation may be ended after 14 days of appropriate antibiotic treatment. In suspected cases, isolation may be terminated if laboratory and clinical findings fail to confirm the diagnosis.
 - b. All articles in contact with a patient and all articles soiled by discharges of a patient shall be disinfected or disposed of in a manner acceptable to the health officer.
 - c. At termination of isolation, the quarters shall undergo terminal disinfection
 - d. All close contacts should have cultures taken and should be kept under surveillance for 7 days. Adult contacts whose occupation involves handling food or close association with children must be excluded from these occupations until shown by bacteriological examination not to be carriers.

116.05 Foodborne Illness

- 1. Class 1 case report required for outbreaks. Some foodborne diseases require case reports for a single case see Appendix A to the <u>Rules and Regulations Governing Reportable Diseases and Conditions.</u>
 - a. Whenever the local health officer shall know of or suspect the existence of an outbreak of illness due to food infection or food poisoning, he/she shall conduct an immediate investigation of all the circumstances.
 - b. The local health officer shall prohibit infected or potentially infected persons from engaging in the preparation or handling of foods or foodstuffs until said health officer is satisfied that said persons are free of pathogenic microorganisms.
 - c. The local health officer shall, upon investigation, prohibit practices in preparation, processing, storing or handling of food or foodstuffs which are known or may be reasonably inferred to be conducive to food poisoning.
 - d. The local health officer shall require compliance of all persons or firms with at least the minimum sanitary requirements of the Mississippi State Board of Health in regard to the physical plant in which or from which perishable foods or foodstuff are offered to the public.

116.06 Hepatitis

- 1. Class 1 case report required for hepatitis A.
 - a. Patients with hepatitis A should be questioned as to whether they work as a foodhandler (including voluntary work) and whether they have children in the household who attend a daycare center. This information shall be a part of the case report.
 - b. The local health officer shall prohibit persons infected or potentially infected with hepatitis A from engaging in the preparation or handling of foods or foodstuffs until said health officer is satisfied that said persons are free of hepatitis A virus.
- 2. Class 2 case report required for acute viral hepatitis other than hepatitis A.

Hansen Disease (Leprosy)

- 1. Class 3 case report required.
 - a. Treatment should be in consultation with the Mississippi State Department of Health for local treatment.
 - b. Contacts of infectious cases are to be examined by the health officer or his/her designee at yearly intervals for 5 years after contact is broken.

116.08 Influenza-Associated Pediatric Mortality

1. Class 1 case report required.

116.09 Measles

1. Class 1 case report required. Effective outbreak control is dependent on immediate telephone report of individual cases.

116.10 Meningitis

1. Class 1 case report required for meningococcal and *Haemophilus influenzae* type b meningitis or other forms of invasive disease, since chemoprophylaxis for high risk contacts is provided by the Department of Health. (usually presents as meningitis or septicemia, or less commonly as cellulites, epigolttitis, osteomyelitis, pericarditis, or septic arthritis.)

116.11 Ophthalmia Neonatorum (Neonatal Gonococcal Ophthalmia)

1. All physicians and midwives attending births must install in the eyes of the newborn 1 drop of a 1 percent solution of silver nitrate within 1 hour after birth except that physicians may elect to use penicillin or other antibiotics in the manner and after the technique which may from time to time be generally accepted by the medical profession as being at least as effective as 1 percent silver nitrate.

116.12 Poisoning

- 1. Class 2 case report required for individual cases.
- 2. For the purpose of reporting, poisoning includes, but is not limited to cases involving observable clinical symptomology or significant clinical laboratory changes as a result of over exposure to drugs, household products, pesticides, agricultural or industrial chemicals, plants, venomous animals or any other toxicant. Reports made to the Mississippi Poison Control Center at the University of Mississippi Medical Center in Jackson (1-800-222-1222) will satisfy this requirement.

116.13 Rabies

1. Class 1 case report required.

2. Control in Animals

a. The Mississippi State Department of Health subscribes to the Compendium of Animal Rabies Control, parts I, II, and III, prepared annually by the National Association of State Public Health Veterinarians. The provisions of this compendium have been endorsed by the CDC, U. S. Public Health Service, Department of Health and Human Services; the American Veterinary Medical Association; the Council of State and Territorial Epidemiologists; and other public and private agencies. The current Compendium is presented as Appendix D to the Rules and Regulations Governing Reportable Diseases and Conditions. The following are state specific modifications to the Compendium.

3. Vaccine Administration

a. All animal rabies vaccines are restricted to use by or under the supervision of a veterinarian or person specifically licensed or designated by the State Board of Health to administer rabies vaccine.

4. Vaccine Selection

a. The current Compendium lists vaccines licensed for use in the United States. Only licensed vaccines shall be used. Vaccines selected for immunizing dogs and cats shall be licensed as providing 3-year immunity.

5. Wildlife Vaccination

a. Vaccination of wildlife is not recommended since no vaccine is licensed for use in wild animals. Offspring of wild animals bred with domestic dogs or cats are considered wild animals.

6. Pre-Exposure Vaccination (Dogs and Cats)

a. All dogs and cats shall be vaccinated against rabies at three months of age, revaccinated one year later and every three years thereafter, using a rabies vaccine approved as providing a 3 year immunity.

7. Post-Exposure Management

- a. Any animal bitten or scratched by a wild, carnivorous mammal or bat that is not available for testing should be regarded as having been exposed to rabies.
- b. <u>Dogs, Cats, and Ferrets</u>: Unvaccinated dogs, cats, and ferrets exposed to a rabid animal should be euthanized immediately. If the owner is unwilling to have this done, the animal should be placed in strict isolation for 6 months and vaccinated 1 month before being released. Animals with expired vaccinations need to be evaluated on a case-by-case basis. Dogs, cats, and ferrets that are currently vaccinated should be revaccinated immediately, kept under the owner's control, and observed for 45 days.

8. Management of Animals that Bite Humans

- a. A healthy dog, cat, or ferret that bites a person shall be confined and observed for 10 days in a manner acceptable to the local health officer or his or her designee. Rabies vaccine shall not be administered during the observation period. Such animals shall be evaluated by a veterinarian at the first sign of illness during confinement. Any illness in the animal shall be reported immediately to the local health department. If signs suggestive of rabies develop, the animal shall be euthanized, its head removed, and the head shipped under refrigeration to the Department of Health Laboratory for examination. Any stray or unwanted dog, cat, or ferret that bites a person may be euthanized immediately, in lieu of 10 days of observation, and the head submitted as described above for rabies examination.
- b. Animals other than dogs, cats, or ferrets that might have exposed a person to rabies should be reported immediately to the health department. This is not to include low risk animals such as small rodents and lagomorphs (e.g., squirrels, rats, mice, gerbils, and rabbits). Prior vaccination of an animal does not preclude the necessity for euthanasia and testing if the period of virus shedding is unknown for that species. Management of animals other than dogs, cats, and ferrets depends on the species, the circumstances of the bite, the epidemiology of rabies in the area, and the biting animal's history, current health status, and potential for exposure to rabies. The need

for euthanizing and testing the animal shall be decided upon consultation with the Epidemiology Program. Post-exposure management of persons should follow the recommendations of the ACIP.

116.14 <u>Sexually Transmitted Diseases - General</u>

- 1. Any person known or suspected of having syphilis, gonorrhea, Chlamydia, chancroid, human immunodeficiency virus (HIV) or other sexually transmissible disease (STD) or suspected of having been exposed to syphilis, gonorrhea, Chlamydia, chancroid, HIV or other STD shall submit to examination as provided in Section 105. Any person who, after due notification, fails or refuses to report for examination at the time and place designated by the health officer shall be subject to prosecution and the local health officer or the Mississippi State Department of Health or its representative may make an affidavit of such fact and cause the issuance of a warrant returnable before any court of competent jurisdiction. All records and reports herein required shall be kept in secret files and disclosed only as required before the court (Section 41-23-29, Mississippi Code of 1972 as amended.).
- 2. It shall be the duty of the local health officer or his or her representative to conduct effective epidemiological actions including initial and follow up interviews, rapid contact and suspect referral to medical examination, satisfactory determination of the source of patient infection and all subsequent infections, and appropriate administration of prophylactic treatment to all at risk critical period contacts.
- 3. Case reports of genital Chlamydia, gonorrhea, chancroid and syphilis shall include date, type of treatment and dose, or if no treatment has been initiated.

4. Syphilis

a. Class 1 case report required.

b. General

- i. Any reactive serologic test for syphilis (STS) shall be reported to the State Department of Health by the laboratory performing the test. Report shall include test result, patient's name, age, race, sex, and address, and name of physician ordering the test.
 - i. RPR or VDRL $\geq 1:8$ Class 1 case report required.
 - ii. Any reactive STS in persons 10 years of age or youngerClass 1 case report required.
 - iii. RPR or VDRL ≤ 1:4 Class 2 case report required.

 <u>MSDH</u> "Laboratory Log Sheet" or a form providing all the same information may be used.

c. Premarital

- i. Every applicant for a marriage license in the State of Mississippi must have a blood test for the detection of syphilis prior to but not more than 30 days before application for a marriage license is made. Said test must be performed by a laboratory approved by the Mississippi State Department of Health and must be interpreted by a duly licensed physician in order to carry out the intent of Section 93-1-5(e), Mississippi Code of 1972 as amended. This information must be supplied to the applicant in duplicate on a standard medical certificate form supplied by the Mississippi State Department of Health except that certificates issued under similar laws in other states shall be acceptable.
 - i. If the applicant's blood test for syphilis is reactive, the interpreting physician shall, before signing the certificate, require such additional testing, evaluation and/or treatment of the applicant as he/she may deem necessary to carry out the intent of the law in regard to the transmission of syphilis.
 - ii. Medical certificates for premarital purposes may be secured by the applicant from any duly licensed physician or county health department in the State of Mississippi or in any other state or territory where the requirements in this respect are not less than those of the State of Mississippi.
 - iii. Applicants in the State of Mississippi for the premarital certificates shall present themselves to the physician of their choice, or to any health department. The physician or health department shall collect from the applicant a specimen of blood suitable for use in performing a standard serologic test for syphilis and said specimen of blood shall be submitted to a laboratory approved by the Mississippi State Department of Health (refer to section iv, below) for the performance of such tests.
 - iv. The Mississippi State Department of Health no longer maintains a list of approved laboratories for premarital testing. The U.S. Department of Health and Human Services Clinical Laboratory Improvement Act (CLIA '88) regulations (and equivalent programs for military, Public Health Service, and VA laboratories) now cover all clinical laboratories in the U.S. Any laboratory currently registered under one of these programs and

- approved in the area of syphilis serology is deemed acceptable to perform blood test for syphilis to meet the premarital testing requirements of the State of Mississippi.
- v. Serologic tests for syphilis approved by the Mississippi State Department of Health for the purpose of premarital testing are: VDRL, RPR, RST and USR, providing the tests are performed in accordance with the published technique as described by the United States Public Health Service's current Manual of Tests for Syphilis or approved supplements.
- vi. Laboratory data forms acceptable to the laboratory performing the test shall accompany the specimen of blood, provided that all data forms submitted under the laws of Mississippi relating to premarital requirements shall have conspicuously written or imprinted on their face the word "Premarital;" in addition, the name and address of the physician or health department submitting the specimen, and the name and address of the laboratory performing the test. A copy of the completed laboratory data form shall be returned to the physician or health department submitting the blood specimen.
- vii. Upon receipt of the laboratory data form by the physician or health department, the physician or health officer shall examine the laboratory data form and prepare an original and one copy of the premarital certificate. In the event of reactive or weakly reactive reports on the laboratory data report, it is expected that the physician or health officer will take such necessary steps as to ensure the accuracy of the medical certificate. The completed certificate shall be given to the applicant.

116.15 Tuberculosis

- 1. Class 1 case report required.
- 2. Human Infections:
 - a. The local health officer shall determine and prescribe for individual cases and contacts the isolation, quarantine restrictions and/or treatment necessary for their protection and that of other people. Should any patient fail to observe the isolation methods prescribed by

the local health officer, said health officer shall quarantine the patient in writing and prescribe therein the procedures to be carried out by said patient. Should the patient break his/her quarantine restrictions, the local health officer may apply by letter outlining the circumstances to the Executive Secretary of the Mississippi State Board of Health and request approval of proceedings to commit the patient to a hospital. Upon approval by the Executive Secretary of the Mississippi State Board of Health, the local health officer may initiate proceedings as provided by law for the forcible commitment of the patient. (Sections 41-35-5, 41-33-7, Mississippi Code of 1972 as amended.)

3. Control in Animals:

a. Bovine tuberculosis may be transmitted to man by infected cattle through close contact or the consumption of raw milk. Milk shall be from dairy herds that comply with tuberculosis requirements set forth in the current Mississippi State Board of Health Regulations, and the Mississippi State Department of Health Regulations Governing the Production and Sale of Milk and Milk Products.

4. Tuberculosis Management in Correctional Institution

The following regulations govern all Mississippi state correctional facilities, city and county facilities housing state prisoners, and privately operated correctional facilities in the state.

- a. "Correctional Institutions" and/or "correctional facility" shall be construed to mean any of the state-operated penitentiaries, privately operated correctional facilities, community work centers, community pre-release centers, restitution centers, county or regional correctional facilities, and/or administrative offices as is applicable to each respective policy.
- b. All inmates shall be medically screened for communicable diseases (including *Mycobacterium tuberculosis* [TB], syphilis, and Human Immunodeficiency Virus [HIV]) to prevent the spread of these diseases within the correctional institutions and to the public. Employees (i.e. full and part-time employees, contract staff and volunteers) shall be screened for tuberculosis infection and disease.
- c. The correctional institution shall establish schedules, protocols, and responsibilities for the testing of inmates and employees to ensure compliance with all relevant Mississippi State Department of Health (MSDH) guidelines. The correctional institution shall appoint a liaison to ensure that all necessary screening is provided to each inmate and employee under its jurisdiction regardless of the individual's physical location.

- d. The director of the correctional institution, in consultation with the correctional institution's medical director, shall issue procedures to ensure that inmates, prior to being transferred into the correctional institution from another correctional institution, a non-state facility, or out-of-state jurisdiction have been properly tested/screened for communicable disease within the previous thirty (30) days. If such testing and screening has not been accomplished, the director shall ensure that these procedures are completed prior to the transfer or upon the receipt of the inmate.
- e. Screening shall include a Rapid Plasma Reagin (RPR) for syphilis, HIV serology, and TB testing, including, TB signs and symptoms assessment, exposure history, two-step Mantoux tuberculin skin test or blood assay for mycobacterium tuberculosis (BAMT) and chest x-ray if indicated. All HIV-Positive inmates and employees shall have an x-ray as part of the medical screening. No inmate shall be placed in the general population until the medical assessment is completed. Any symptomatic inmate shall remain in respiratory isolation until TB test results are known and active tuberculosis disease has been ruled out. Documentation of these screening tests shall be maintained for all inmates in a correctional institution. Test results shall be reported to the MSDH.
- f. Screening, latent therapy, active treatment and treatment follow-up of inmates and employees for tuberculosis shall follow the policies and procedures included in the latest revision of the Tuberculosis Manual of the MSDH. All latent and active TB treatment of the inmates shall be directly observed by a health care provider.
- g. The correctional institution's medical director, in order to contain communicable disease and/or enforce screening schedules, with the approval of the correctional institutional superintendent and/or classification director shall have the authority to:
 - i. Place inmates in quarantine
 - ii Suspend employees
 - iii. Move inmates between approved housing locations or to approved medical facilities
 - iv. Issue procedures for the care and treatment of inmates and employees with communicable diseases
- Each correctional institution or correctional facility shall provide a complete, legible and accurate Tuberculin Testing Summary (MSDH Form 181) summarizing the correctional facility's tuberculin testing activity and containing a roster of all inmates and employees that were

first identified as having a significant Mantoux tuberculin skin test reaction* or positive BAMT with in the reporting period. This roster shall include comments and conclusions concerning the individual follow-up of each person listed. The Tuberculin Testing Summary, with appropriate notations, shall be logged in the Office of the State Tuberculosis Program on or before March 15th of each year for the twelve (12) months proceeding January 31st of that year.

Summary of TB screening and procedures

- i. All inmates shall have a two-step Mantoux tuberculin skin test or BAMT. Each Mantoux tuberculin skin test shall be administered using five tuberculin units (5 t.u.) of purified protein derivative (PPD) unless individually excluded by a licensed physician or nurse practitioner due to medical contraindications or exceptions noted herein. BAMT testing shall be collected and results interpreted by personnel trained and certified in the procedure BAMT results shall be given as EIA positive, Negative or Indeterminate. All Mantoux tuberculin skin test shall be administered and read by personnel trained and certified in the procedure and the results recorded in millimeters of induration. Exception to the tuberculin skin test requirements may be made if:
 - i. The individual is currently receiving or can provide documentation of having successfully completed a course of therapy for latent tuberculosis approved by the State Tuberculosis Program.
 - ii. The individual is currently receiving or can provide documentation of having successfully completed a course of multi-drug chemotherapy approved by the State Tuberculosis Program for active tuberculosis disease, or
 - iii. The individual has a documented previous significant tuberculin skin test reaction* or positive BAMT.
- j. The tuberculin skin test status of all employees shall be documented in the individual's personnel record. The BAMT or the first step of a two-step Mantoux tuberculin skin test shall be performed (i.e. administered and read) on all new employees (and rehires) within thirty (30) days prior to the first day of employment. The Mantoux tuberculin skin test or BAMT shall be administered and read by personnel trained and certified in the procedure. The results of the tuberculin skin test shall be recorded in millimeters of induration. The results of the BAMT shall be recorded as EIA positive, negative or indeterminate. An employee shall not have contact with inmates or be

allowed to work in areas of the correctional institution to which inmates have routine access prior to the reading of the first-step of a two-step Mantoux tuberculin skin test or having a BAMT and completing an exposure history and symptom assessment. The results of both steps of the two-step Mantoux tuberculin skin test or BAMT shall be documented in the individual's personnel record within fourteen (14) days of employment. Exception to the tuberculin skin test requirement may be if:

- The individual is currently receiving or can provide documentation of having successfully completed a course of therapy for latent tuberculosis infection approved by the State Tuberculosis Program. Or
- ii. The individual is currently receiving or can provide documentation of having successfully completing a course of multi-drug chemotherapy approved by the State Tuberculosis Program for active tuberculosis disease, or
- iii. The individual has a documented previous significant tuberculin skin test reaction* or positive BAMT
- k. All inmates and employees with a previous significant Mantoux tuberculin skin test* or positive BAMT and/or symptoms suggesting TB (e.g. cough, sputum production, chest pain, anorexia, weight loss, fever, night sweats, especially if symptoms last three weeks or longer, regardless of the size of the skin test), shall receive a chest x-ray and be evaluated by a physician or nurse practitioner within 72 hours. Individuals found to have a significant Mantoux tuberculin skin test or positive BAMT, signs and symptoms of tuberculosis or a chest x-ray suggestive of active tuberculosis shall be placed in respiratory isolation according to MSDH policies, reported to MSDH and evaluated by physician or nurse practitioner for tuberculosis therapy.
- 1. Individuals found to have a significant Mantoux tuberculin skin test or positive BAMT or with a history of a previous significant Mantoux tuberculin skin test or positive BAMT and a chest x-ray not suggestive of active tuberculosis, shall be evaluated by a physician or nurse practitioner for latent tuberculosis therapy. Individuals with significant Mantoux tuberculin skin tests or positive BAMT and no evidence of active TB disease should be reminded periodically about the symptoms of tuberculosis and the need for prompt evaluation of any pulmonary symptoms of tuberculosis. A tuberculosis symptom assessment shall be documented as part of the annual health screening. No additional follow-up for these individuals is indicated unless

- symptoms suggestive of active tuberculosis develop; specifically, routine annual chest x-rays are not indicated.
- m. Employees found to have a positive/significant reaction* to the skin test or a positive BAMT and no signs or symptoms of tuberculosis disease and a negative chest x-ray shall, as a condition of employment, have thirty (30) days to report to the MSDH office in their county of residence to confirm appropriate follow-up testing has been completed and receive treatment, if indicated. The employees shall provide the director or designee with a written statement from the MSDH verifying compliance with the directives set forth by the correctional institution's medical director and this regulation.
- n. All inmates and employees who do not have a significant Mantoux tuberculin skin test or positive BAMT shall be retested annually within thirty (30) days of the anniversary of their last Mantoux tuberculin skin test. Inmates and employees exposed to an active infectious case of TB between annual tuberculin skin test shall be treated as contacts and be managed appropriately. All contacts to an active tuberculosis case shall have HIV testing as part of the exposure management.

*Criteria for a significant tuberculin skin test

Reaction > 5 mm(greater than or equal to 5mm)

- High risk contact to an active tuberculosis case
- HIV-positive persons
- Fibrotic changes on chest radiograph consistent with prior TB Patients with organ transplants and other immunosuppressed patients (receiving the equivalent of \geq 15 mg. of prednisone for 1 mo or morerisk of TB in patients treated with corticosteroids increases with higher doses and longer duration) Reaction \geq 10 mm (greater than or equal to 10 mm)
- any other prisoner or employee of the prison

116.16 Typhoid Fever

- 1. Class 1 report required.
 - a. In case of typhoid fever, isolation shall be maintained for not less than 4 weeks from date of onset, and urine and feces cultures for release from isolation shall not be taken earlier. Release from isolation and health department supervision shall be on the basis of not less than 3 consecutive negative cultures obtained from authenticated specimens of feces taken not less than 24 hours apart at least 48 hours after any antibiotic, and not earlier than one month after onset. If any one of this series is positive, a temporary carrier status shall be considered established
 - b. During the first 6 months of the temporary carrier status, the patient may again be tested for release by securing not less than 3 consecutive negative cultures obtained from authenticated specimens at intervals of 1 month. If the patient is positive at the 6th month or if no test is made, the case is classed as a permanent carrier. Final release from permanent carrier status must be with the advice and consent of the State Epidemiologist, and cannot be considered unless 3 consecutive monthly cultures obtained from authenticated specimens collected at least 48 hours after any antibiotic, have been negative on examination by the Department of Health Laboratory or other laboratories approved by the Department of Health.
 - c. Whenever the typhoid carrier status shall be declared by the local health officer and there is no patient history of typhoid during the preceding year, the patient shall be classed as a permanent carrier.
 - d. No person classed as a carrier shall engage in handling of foods or foodstuffs for public consumption, nor shall such carrier offer to perform such services for any family (other than his or her own) or for any other group or institution, either private or public. No such carrier shall engage in providing domestic services for hire or provide direct client care in a nursing home or child day care center without the advice and written consent of the health officer.
 - e. When any person is declared to be a carrier of typhoid, the local health officer shall collect pertinent information about the carrier. The necessity for imposing restrictions on the patient's activities shall be explained to the patient and the patient shall signify in writing his or her willingness to observe the carrier agreement and restrictions. A copy of the carrier information shall be forwarded immediately to the

- Epidemiology Program, Mississippi State Department of Health, in Jackson.
- f. When any known carrier of typhoid moves from the county, a copy of the carrier's history and agreements, together with the prospective future address of the carrier, shall be forwarded to the Mississippi State Department of Health by the local health officer of the county from which the carrier is moving. The original copy of the history and agreement shall remain as a part of the files of the county health department of the county from which the carrier has moved.
- g. All family or other close contacts of a case of typhoid or other salmonella infection shall submit specimens of their feces as required by the health officer and submit to any reasonable examination as may aid in the search for unknown carriers and sub clinical cases.
- h. All family or other close contacts of a carrier of typhoid or other salmonella infection shall be prohibited from handling foods or foodstuffs for public consumption until contact is broken and repeated negative laboratory examinations are reported. For salmonelloses, except typhoid, a series of 2 negative feces cultures taken not less than 24 hours apart at any time after contact is broken will satisfy this provision. For typhoid fever a series of 2 negative stools taken not less than 24 hours apart and not less than 14 days after contact is broken will satisfy this provision.
- i. The owner or operator of a house, hotel, apartment or other institution in which a typhoid carrier resides shall provide a sanitary method of excreta disposal which will not subject other occupants of the house, apartment, hotel or other institution or the general public to typhoid or paratyphoid infection. If the owner or operator of the property on which a carrier resides fails for due cause to provide such sanitary methods of excreta disposal, the carrier shall provide such facilities as meet approval of the Mississippi State Department of Health.
- j. Any typhoid carrier planning to change his/her place of residence or his/her occupation shall notify the local health officer in writing of such anticipated change.
- k. Whenever a case or carrier of typhoid is diagnosed it shall be the duty and responsibility of the local health officer to conduct a search for the source of the infection and for the food, water or person from whom it was acquired. Strict measures for assuring the safety of the water and milk supplies and of all foodstuffs should be instituted.
- 1. Mandatory report and surveillance required.

117 Penalty for Violation of Rules and Regulations Regarding Reportable Diseases

Any physician, dentist or other person who shall fail, neglect, or refuse to comply with, or shall falsify any report, or shall violate any of the Rules and Regulations of the Mississippi State Board of Health shall, upon conviction, be guilty of a misdemeanor and subject to the penalty provided by law.

118 MISSISSIPPI HEALTHCARE DATA REGISTRY SYSTEM

118.01 REPORTING REQUIREMENTS AND PROCEDURES

- 1. Authority-Mississippi Code Annotated § 41-63-4 requires certain licensed health care facilities operating in the state of Mississippi to report information on patient health care to the Mississippi State Department of Health. Further, Mississippi Code Annotated § 41-7-185 requires providers of institutional health services and home health services to make available statistical information or such other requested information by the Mississippi State Department of Health.
- 2. Purpose -The Mississippi State Department of Health (MSDH), acting as the state's public health authority, is required to design and establish a registry program concerning the condition and treatment of persons seeking medical care in the state of Mississippi. MSDH must collect, analyze and disseminate these health care data in order to improve the quality and efficiency of medical care.
- 3. Reporting Responsibility-Each of the following licensed health care facilities in the state of Mississippi shall be required to report the specified health care data described in these rules and regulations:
 - a. Hospital Facilities See Part 3;
 - b. Ambulatory Surgical Facilities See Part 4 [Reserved];
 - c. Outpatient Diagnostic Imaging Centers See Part 5 [Reserved];
 - d. Other See Part 6 [Reserved];
- 4. Reporting Contact-In order to facilitate communication and problem solving, each reporting facility must designate a person as contact and advise the Department from time to time of any changes to such contact information. Contact information shall include the office name, telephone number, job title and name of the person assigned this responsibility to the MSDH.
- 5. Penalties for Not Reporting-

- The MSDH is authorized to assess penalties as provided by statute pursuant to Mississippi Code Annotated § 41-63-4 Paragraph (12) which states, "A person or organization who fails to supply data required under this section is liable for a civil penalty of Five Cents (5ϕ) for each record for each day the submission is delinquent. A submission is delinquent if the department does not receive it within thirty (30) days after the date the submission was due. If the department receives the submission in incomplete form, the department shall notify the provider and allow fifteen (15) additional days to correct the error. The notice shall provide the provider an additional fifteen (15) days to submit the data before the imposition of any civil penalty. The maximum civil penalty for a delinquent submission is Ten Dollars (\$10.00) for each record. The department shall issue an assessment of the civil penalty to the provider. The provider has a right to an informal conference with the department, if the provider requests the conference within thirty (30) days of receipt of the assessment. After the informal conference or, if no conference is requested, after the time for requesting the informal conference has expired, the department may proceed to collect the penalty. In its request for an informal conference, the provider may request the department to waive the penalty. The department may waive the penalty in cases of an act of God or other acts beyond the control of the provider. Waiver of the penalty is in the sole discretion of the department;" and
- b. Failure of any health care facility or other person or entity covered by the "Mississippi Health Care Certification of Need Law of 1979", Mississippi Code Annotated § 41-7-171 through § 41-7-209, to report any requested information, data or otherwise failure to report under these provisions, shall be in violation of the "Mississippi Health Care Certification of Need Law of 1979" and subject to violations provided in Mississippi Code Annotated § 41-7-209.
- 6. Confidentiality-Information maintained in the Mississippi Healthcare Registry Data System shall be confidential and shall not be distributed or released except with the permission of MSDH in accordance with its established policies and procedures. Violation of confidentiality requirements may be subject to severe civil and/or criminal penalties.

The release of identifiable patient health information may be made by MSDH only to the facility that initially reported the identifiable information, upon the written request of such facility. Any request by any other party for the release of identifiable information shall be reviewed by the MSDH Data Use Council (described below), and the Data Use Council may approve such request only for the purpose of public health

assessment or research under such guidelines and stipulations as may be necessary to maintain confidentiality requirements.

Prior to the dissemination or release of any data analysis or statistical reports concerning registry information, including any release to MSDH divisions or programs, the Data Use Council may review the methods and procedures deemed necessary to maintain the privacy and confidentiality of patient records, including the system security requirements.

The MSDH shall be required to regularly monitor the physical security of the registry, to train personnel concerning the system's confidentiality standards, to limit access to the registry information solely to authorized personnel, and to implement password and encryption protections in the system.

- 7. Protected Health Information-The disclosure of protected health information by a reporting facility pursuant to these rules and regulations shall be recognized as a disclosure to a public health authority as required by law, pursuant to the Health Insurance Portability and Accountability Act and the Privacy Rules promulgated there under at 45 CFR Sections 164.512(a) and (b).
- 8. Data Use Council-The State Health Officer will create a Data Use Council consisting of not less than five individuals to recommend policies and procedures regarding the release of any registry data to MSDH divisions and programs, to the public, to researchers and to industry. Appointments to the Council shall be made at the sole discretion of the State Health Officer for such terms as may be established by the policies and procedures of the MSDH.

MSDH divisions and programs may, with the consent of the Data Use Council, use patient abstract data to assist in fulfilling its public health mission. These data will not be re-released in any form by the program without the prior authorization of the Data Use Council. Authorization for subsequent release shall be considered only if the proposed release does not identify a patient.

9. Temporary Waiver of Reporting Requirement-With respect to any licensed health care facility otherwise required to report data or other information to the MSDH pursuant to these rules and regulations, the MSDH shall be authorized to temporarily waive reporting requirements due to system requirements of MSDH or the reporting facility, or in the case of irregularities or errors involving data delivery. Any waiver of the reporting requirements must be made in writing by the MSDH and notice of the termination of any waiver shall be provided to the applicable reporting facility, at which time these Regulations shall become applicable to such facility.

10. Charges and Fees for Access to Data-Subject to the confidentiality requirements of these Regulations, the MSDH may develop reports and data analyses based upon registry data which may be released to the public. The reports may be published or disseminated for a reasonable charge, or without charge at the discretion of MSDH.

At the time of the promulgation of these Regulations, the MSDH shall refrain from assessing any charges to reporting facilities for the collection of health care data. Nothing shall prohibit the State Board of Health from authorizing, at any future date in accordance with its statutory authority, the assessment of reasonable charges for the collection of such data, or the reporting of specified health care data to the MSDH for purposes of the registry.

118.02 ADMINISTRATIVE RULES AND PROCEDURES

Assertion of Administrative Appeal Rights. In the case of the Department's enforcement of any of the measures described in these Regulations, if the matter is disputed by the affected party or parties and the Department and the party have been unable to resolve the dispute, the affected party or parties shall petition the Department to appear at an administrative hearing before a hearing officer appointed by the State Health Officer.

Content and Form of Petition. The petition must be in writing and be submitted to the Department within 15 business days of the date upon which the petitioner received notice of the imposition of the enforcement measures. The petitioner must state in the petition the reasons for the appeal, and the petition must describe any facts which may be in dispute and must identify any grievances which are deemed by the petitioner to be genuine and substantial.

Opportunity to Remedy Grievances. If the Department is unable to resolve the disputed facts and remedy the petitioner's grievances within 5 business days of the Department's receipt of the petition, the unresolved matters shall be reviewable by the hearing officer at an administrative hearing conducted in accordance with these Regulations. No unresolved matters shall be reviewable in the event that the Department shall terminate its enforcement action prior to the commencement of the hearing.

1. General Principles for Administrative Reviews

With respect to matters brought before the Department or the State Board of Health for administrative review, whether or not such review is initiated by the Department, a notice of the proceeding shall be prepared by the Department and the petitioner or the affected party or parties shall be afforded an opportunity to appear at such proceeding in accordance with the Regulations set forth in this Part 3.

Any party who shall participate in the administrative proceeding shall be entitled to:

- a. Timely scheduling of the hearing if appealed by the petitioner in accordance with Section 201, but in any event no more than 15 business days after the date of the Department's receipt of the petition;
- b. Representation by legal counsel, chosen in the discretion of such party and at such party's sole cost and expense;
- c. Submission of testimony and documentary evidence, and presentation of argument and rebuttal with respect to the issues;
- d. Conduct examination and cross-examination of witnesses to elicit a full and fair disclosure of the facts; and
- e. Demand a timely completion of the proceedings.
- 2. Notice of Hearing. Notice of Hearing shall be served upon a petitioner or any other affected party in the same manner as authorized for the service of a Health Officer's Order or in such other manner as may be deemed reasonable and prudent by the hearing officer in order to properly notify the petitioner that a hearing has been scheduled.
- 3. Date of Hearing. Unless otherwise provided by law, the notice of hearing must be given at least ten (10) days prior to the hearing date unless this notice period is waived by the affected parties in the interest of expediting the administrative review. Unless otherwise provided by law, proof of receipt of notice shall not be a required condition for the conduct of the hearing.
- 4. Assignment of Hearing Officer. Within ten (10) days of the date on which the Department shall give Notice of Hearing, the State Health Officer or his authorized designee shall appoint the hearing officer assigned to hear the matter, and notice of such appointment shall be provided to all parties.
- 5. Conduct of Hearings. The hearing officer shall preside at the hearing, and shall rule on all questions of applicable procedure and submission of evidence in accordance with the policies and procedures approved by the hearing officer. The hearing officer may issue an order using particular provisions of the Mississippi Rules of Civil Procedure and related local rules for guidance; however, formal adherence to said Rules shall not be mandated. The hearing officer may waive the application of any of these rules to further administrative convenience, expedition, and economy if the waiver does not conflict with law, and the waiver does not cause undue prejudice to any party.

- 6. Rules of Evidence. The Mississippi Rules of Evidence shall be used as a general guide for the presentation of evidence. However, any evidence which reasonably appears to be relevant and probative to the issues may be allowed in the discretion of the hearing officer, notwithstanding its inadmissibility under said Rules, unless the evidence offered is clearly of a privileged nature.
- 7. Authority of Hearing Officer. The hearing officer shall have authority to do all things conformable to law that may be necessary to enable the officer effectively to discharge the duties of office, including, but not limited to, the authority to make final findings of fact and a written recommendation to the Department as to which enforcement actions or other restrictions, if any, should apply to the party or parties.
- 8. Discovery. Discovery shall be limited to non-privileged documents. Depositions and requests for admissions may be directed, issued, and taken on order of the Department for good cause shown. These orders or authorizations may be challenged or enforced in the same manner as subpoenas. All requests for discovery must be timely and in writing. All disputes regarding the privileged nature of a document shall be resolved by the designated hearing officer prior to the commencement of the hearing.
- 9. Public Access. Unless otherwise provided by law, all hearings are open to the public.
- 10. Failure of Party to Appear for Hearing. If a party fails to appear at a hearing, the hearing officer may proceed with the presentation of the evidence of the appearing party, or vacate the hearing and return the matter to the Department for any further action.

11. Proof.

- a. Standard of proof. Unless otherwise provided by law, the standard of proof is a preponderance of the evidence.
- b. Burden of Proof. Unless otherwise provided by law:
 - i. The party asserting a claim, right, or entitlement has the burden of proof;
 - ii. A party asserting an affirmative defense has the burden of establishing the affirmative defense; and
 - iii. The proponent of a motion shall establish the grounds to support the motion.

- 12. Ex Parte Communications. A party shall not communicate, either directly or indirectly, with the hearing officer about any substantive issue in a pending matter unless:
 - a. All parties are present;
 - b. It is during a scheduled proceeding, where an absent party fails to appear after proper notice; or
 - c. It is by written motion with copies to all parties.
- 13. Conflict Issues. All allegations of conflict or bias on the part of the appointed hearing officer must be filed at least three (3) business days prior to the hearing date. The State Health Officer who appointed the hearing officer shall then consider the assertion of conflict or bias, and shall issue a written opinion prior to the commencement of the hearing.
- 14. Hearing Record. A stenographic record of the hearing shall be made by a reporter chosen by the hearing officer. No transcript or other record of the proceeding shall be required to be maintained by the Department unless (i) required by statute or other rule, (ii) ordered by the hearing officer, or (iii) agreed in writing by all of the parties.
- 15. Remedies for Non-compliance with Rules. If a respondent shall fail to fully comply with the requirements of the hearing officer's policies and procedures or other rulings, the hearing officer shall be authorized to impose fines in an amount not to exceed \$500 per occurrence and such other remedies as may be deemed appropriate by the hearing officer for the effective administration of those duties and responsibilities assigned to such officer.
- 16. Appeals. Any person adversely affected by a decision of the Department shall have a right to appeal the decision through an appropriate and timely court action against the Department and/or its agents, consistent with applicable laws and jurisdictional requirements. Unless applicable law provides a longer period of time in which to assert any appeal, no appeal of a decision of the Department shall be taken unless it is filed with a court having jurisdiction within thirty (30) days of the date of the Department's decision.

118.03 HOSPITAL REPORTING

1. Purpose -A statewide Hospital Discharge Data System (HDDS) is one of the most important tools for addressing a broad range of health policy issues, including the improvement of the quality and efficiency of medical care. "Discharge data" is defined as the consolidation of complete billing, medical, and personal information describing a patient or resident, the services received, and charges billed for a single hospital

- stay. The requirements for the collection and submission of data as described shall also apply to those non-federal acute care hospitals located in Alabama, Arkansas, Louisiana, and Tennessee. Data submitted by these non-Mississippi hospitals shall relate exclusively to those patients who are Mississippi residents.
- 2. Reporting Required-Each reporting facility will report discharge data to the MSDH on every inpatient and outpatient discharged, to include those seen in the Emergency Department. Hospitals may submit data to MSDH directly or through the Mississippi Hospital Association (MHA) for submission to the HDDS, as specified by law. The submission of similar collected data to the Mississippi Hospital Association (MHA) shall not relieve the reporting facility of its reporting requirements to the MSDH unless written approval for such reporting methodology is provided by the MSDH.
- 3. Data Elements -The Mississippi HDDS is based on the Health Care Finance Administration (HCFA) UB-04 or the most recent version and additional selected information routinely collected by health care facilities on each patient. Data elements are listed in the HDDS policy manual.
- 4. Quality Assurance-MSDH Data Use Council will develop guidelines for quality assurance and accuracy that each reporting hospital will be required to follow.
- 5. Time of Reporting and Methodology- Reporting facilities shall submit data for each calendar month based upon discharges occurring during such month. Collected data shall be submitted to the MSDH on or before the 15th day of the following month.

Questions concerning any reporting methodology or guidelines shall be reasonably addressed by the MSDH, and administrative remedies shall be available to any facility concerning any disputes.

CERTIFICATION OF REGULATION

This is to ce	rtify 1	that the a	bove <u>Ru</u>	les and Regi	ulation	s Gove	rnin	g Repo	<u>rtab</u>	<u>le Dise</u>	ase	s and
Conditions	was	adopted	by the	Mississippi	State	Board	of	Health	on	April	9,	2008
to become ef	fectiv	e May 10	0, 2008_	<u>-</u>								
Witness my l	nand a	and seal o	f office,	thisday of	f	2008.						
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Appendices to the Rules and Regulations Governing Reportable Diseases and Conditions

Appendix A List of Reportable Diseases and Conditions

Appendix A. List of officially reportable diseases and conditions

The following diseases or conditions are hereby declared to be reportable.

Class 1:

Diseases of major public health importance which shall be reported directly to the Department of Health by telephone within 24 hours of first knowledge or suspicion. Class 1 diseases and conditions are dictated by requiring an immediate public health response. Laboratory directors have an obligation to report laboratory findings for selected diseases (Refer to Appendix B).

Any Suspected Outbreak (including foodborne and waterborne outbreaks)

Anthrax
Arboviral infection including but not limited to California grp., Eastern Equine Encephalitis, LaCrosse, Western Equine Encephalitis, St. Louis encephalitis,

West Nile Virus

Botulism (includes foodborne, infant or

wound)
Brucellosis
Chancroid
Cholera

Creutzfeldt-Jakob Disease, including new variant

Diphtheria

Escherichia coli 0157:H7 Encephalitis (human)

Glanders

Hemolytic Uremic Syndromepost-diarrheal (HUS)

Hepatitis A

HIV infection- including AIDS Influenza-Associated Pediatric

Mortality (<18 years) Invasive Disease Due to:

Neisseria meningitidis or

Haemophilus influenzae type b*

Measles

Melioidosis Pertussis Plague

Poliomyelitis Psittacosis O Fever

Rabies (human or animal)

Ricen intoxication (castor beans)

Smallpox

Staphylococcus aureus

vancomycin resistant (VRSA) vancomycin intermediate (VISA)

Syphilis (including congenital)

Tuberculosis Tularemia Typhoid Fever Typhus Fever

Varicella Infection, Primary, in patients >15 years of age

Viral hemorrhagic fevers (filoviruses

[e.g. Ebola, Marburg] and arenaviruses [e.g., Lassa,

Machupo]) Yellow Fever

Any unusual disease or manifestation of illness, including but not limited to the appearance of a novel or previously controlled or eradicated infectious agent, or biological or chemical toxin.

*usually presents as meningitis or septicemia, or less commonly as cellutlites, epiglottitis, osteomyelitis, pericarditis or septic arthritis.

Class 2: Diseases or conditions of public health importance of which individual cases shall be reported by mail, telephone or electronically, within 1 week of diagnosis. In outbreaks or other unusual circumstances they shall be reported the same as Class 1. Class 2 diseases and conditions are those for which an immediate public health response is not needed for individual cases.

Chlamydia trachomatis, genital infection

Dengue Ehrlichiosis

Enterococcus, invasive infection,

vancomycin resistant

Gonnorhea

Hepatitis (acute, viral only) Note -

Hepatitis A requires Class 1 Report

Legionellosis Listerioisis Lyme borreliosis

Malaria

Meningitis **other** than Meningococcal or

Haemophilus influenzae type b

Mumps

M. Tuberculosis Infection (positive TST) in children<15 years of age

Noncholera vibrio disease

Poisonings*(including elevated blood lead

levels**)

Rocky Mountain Spotted Fever Rubella (including congenital)

Salmonellosis Shigellosis

Spinal Cord Injuries

Streptococcus pneumoniae, invasive infection, antibiotic resistant
Streptococcus pneumoniae, invasive infection in children<5 years of age

Tetanus Trichinosis

Viral Encephalitis in horses and ratities

Except for rabies, and equine encephalitis, diseases occurring in animals are not required to be reported to the Department of Health.

Class 3: Laboratory based surveillance. To be reported by laboratory only. Diseases or conditions of public health importance of which individual laboratory findings shall be reported by mail, telephone, or electronically within one week of completion of laboratory test (refer to Appendix B).

Blastomycosis

Blood Lead test results

Campylobacteriosis

Hansen Disease (Leprosy)

Hepatitis C infection

Histoplasmosis

Cryptosporidiosis Nontuberculous Mycobacterial Disease

^{*}Reports for poisonings shall be made to Mississippi Poison Control Center, UMMC 1-800-222-1222

^{**}Elevated Blood Levels should be reported to the MSDH Lead Program at 601-576-7447.

Class 4 Diseases of public health importance for which immediate reporting is not necessary for surveillance or control efforts. Diseases and conditions in this category shall be reported to the Mississippi Cancer Registry within six months of the date of first contact for the reportable condition.

The National Program of Cancer Registries at the Centers for Disease Control and Prevention requires the collection of certain diseases and conditions. A comprehensive reportable list including ICD9CM codes is available on the Mississippi Cancer Registry website, http://mcr.umc.edu/documents/Reportablecasesafter1006.pdf

Each record shall provide a minimum set of data items which meets the uniform standards required by the National Program of Cancer Registries and documented in the North American Association of Central Cancer Registries (NAACCR)

Appendix B

Laboratory Results That Must be Reported to the Mississippi State Department of Health

Laboratory Results That Must be Reported to the Mississippi State Department of Health

Laboratories shall report these findings to the Mississippi State Department of Health at least WEEKLY. Diseases in bold type shall be reported immediately by telephone. Isolates of organisms marked with a dagger (†) should be sent to the Mississippi State Department of Health Public Health Laboratory. All referring laboratories should call the Public Health Laboratory prior to shipping any isolate (601-576-7582)

Positive Bacterial Cultures or Direct Examinations

Result Reportable Disease Any bacterial agent in CSF bacterial meningitis

Bacillus anthracis† Anthrax Bordetella pertussis **Pertussis** Borrelia burgdorferi† Lyme disease Brucella species† Brucellosis Burkholderia mallei† Glanders Burkholderia pseudomallei† Melioidosis Campylobacter species campylobacteriosis

Chlamydia psittaci **Psittacosis**

Chlamydia trachomatis Chlamydia trachomatis genital infection

Clostridium botulinum†** **Botulism** Clostridium tetani Tetanus Corynebacterium diphtheriae† Diphtheria Coxiella burnetii† Q fever

Enterococcus species* enterococcus infection, invasive vancomycin resistant

Escherichia coli O157:H7† E coli O157:H7 infection

Francisella tularensis† Tularemia Haemophilus ducrevi Chancroid

Haemophilus influenza type b †*(not from H. influenzae infection, invasive

throat, sputum) Legionella species Legionellosis Listeria monosytogenes† Listeriosis

nontuberculous mycobacterial Mycobacterium species disease

Mycobacterium tuberculosis **Tuberculosis** Neisseria gonorrhea Gonorrhea

Neisseria meningitidis †*(not from throat, meningococcal infection, invasive

sputum)

Typhus fever Rickettsia prowazekii

Rickettsia rickettsii Rocky Mountain spotted fever

Salmonella species, not S. tvphi Salmonellosis Salmonella typhi† Typhoid fever Shigella species Shigellosis

vancomycin resistant Staphylococcus aureus (VRSA) or

Staphylococcus aureus- vancomycin resistant or

Streptococcus pneumoniae* pneumococcal infection, invasive in children < 5 or

antibiotic resistant

vancomycin Intermediate Staphylococcus aureus (VISA)

Vibrio cholerae 01† Cholera Vibrio species† Vibrio infection Plague

Yersinia pestis†

vancomycin intermediate resistant

^{*} Specimen obtained from a normally sterile site (usually blood or cerebrospinal fluid, or, less commonly, joint, pleural, or pericardial fluid). Do not report throat or sputum isolates.

[†] Isolates of organism should be sent to the Mississippi State Department of Health Public Health Laboratory. All referring laboratories should call the Public Health Laboratory at (601)-576-7582 prior to shipping any isolate.

^{**}Contact the Mississippi State Department of Health, Epidemiology Program at 601-576-7725 or the Public Health Laboratory (601)576-7582 for appropriate tests when considering a diagnosis of botulism.

Laboratory Results That Must be Reported to the Mississippi State Department of Health

Laboratories shall report these findings to the Mississippi State Department of Health at least **WEEKLY**. Diseases in bold type shall be reported immediately by telephone. Confirmatory tests for some of these may be obtained by special arrangement through the Epidemiology Program at 601-576-7725

Positive Serologic Tests

Arboviral agents including but not limited to:

California encephalitis
Eastern equine encephalitis
La Cross encephalitis
St. Louis encephalitis
Western equine encephalitis
West Nile encephalitis

Brucellosis

Cholera

Chlamydia trachomatis genital infection

Dengue

Ehrlichiosis

hepatitis A (anti-HAV IgM)

hepatitis B (anti-HBc IgM)

hepatitis C

HIV infection (refer to Section 113)

Legionellosis'

Lyme disease

Malaria

Measles

Mumps

Plague

Poliomyelitis

Psittacosis

Rocky Mountain spotted fever

Rubella

syphilis (refer to Section 116)

Smallpox

Trichinosis

yellow fever

Serologic confirmation of an acute case of legionellosis can not be based on a single titer. There must be a four-fold rise in titer to >1:128 between acute and convalescent specimens.

Laboratory Results That Must be Reported to the Mississippi State Department of Health

Laboratories shall report these findings to the Mississippi State Department of Health at least **WEEKLY**. **Diseases in bold type shall be reported immediately by telephone.** The dagger † indicates the positive specimens may be submitted to the Mississippi Public Health Laboratory for confirmation.

Positive Parasitic Cultures or Direct Examinations

Result Reportable Disease Condition

any parasite in CSF† parasitic meningitis

Cryptosporidium parvum cryptosporidiosis

Plasmodium species† malaria

Positive Fungal Cultures or Direct Examinations

Result Reportable Disease Condition

any fungus in CSF Fungal meningitis

Blastomyces dermatitidis blastomycosis

Histoplasma capsulatum histoplasmosis

Positive Viral Cultures or Direct Examinations

Result Reportable Disease Condition

any virus in CSF viral meningitis

Arboviral agents including but not

limited to:

California encephalitis virus California encephalitis

La Cross encephalitis virus

La Cross encephalitis

St. Louis encephalitis (SLE)

Western equine encephalomyelitis virus Western equine encephalitis (WEE)

West Nile virus West Nile encephalitis (WNV)

dengue virus, serotype 1, 2, 3, or 4
polio virus, type 1, 2, or 3
variola virus

Dengue
poliomyelitis
Smallpox

Filoviruses Viral hemorrhagic fevers
Arenaviruses Viral hemorrhagic fevers

yellow fever virus Yellow fever

Positive Blood Chemistries

blood lead levels (venous) of $> 15 \mu g/dl$ in children less than 16 years of age blood lead levels (venous) of $> 25 \mu g/dl$ in those 16 years of age or older

Positive Toxin Identification

Ricin toxin from *Ricinus communis* (castor beans) Surgical Pathology Results

Creutzfeldt-Jakob Disease, including new variant

Malignant Neoplasms

Hansen disease

Human rabies

Trichinosis

Tuberculosis

Appendix C

Case Definitions for Surveillance

Adapted from Centers for Disease Control and Prevention

Case definitions for Infectious conditions

under public health surveillance

MMWR 1997;46(No. RR-10)

Introduction and Comments

The following selected surveillance case definitions are each reprinted in toto. The definitions were originally presented in a supplement to the CDC's *Morbidity and Mortality Weekly Report*. The original document contains two separate lists; one for those conditions under surveillance for the National Notifiable Disease Surveillance System (NNDSS) and the other for other conditions for which many states have their own surveillance needs. The definitions provide uniform criteria for state health department personnel to use when reporting to the NNDSS. The selected definitions reprinted in this appendix are alphabetized from both lists to reflect those conditions declared reportable in Mississippi. The complete list contains definitions for conditions not reportable in Mississippi and these conditions were omitted to prevent confusion on the part of disease reporters. A complete copy of *Cases Definitions for Infectious Conditions under Public Health Surveillance* may be obtained by contacting the Epidemiology Program (601) 576-7725 and is also available from the CDC Internet site at WWW.CDC.GOV.

The surveillance case definitions were developed in collaboration with epidemiologists at CDC and the Council of State and Territorial Epidemiologists (CSTE). The original list of definitions was published in 1990. Through an ongoing process, the list has been refined, updated and new or emerging conditions added. Each addition or change is approved by vote of the CSTE membership and endorsed for use by the Association of State and Territorial Public Health Laboratory Directors (ASTPHLD). A revision date is listed for each case definition that has been revised. Newly generated case definitions that have not been published previously are designated as "adopted" on the specified date. Future additions or significant changes to the definitions will be published on the Mississippi State Department of Health's website at www.msdh.state.ms.us and shall serve as official notification until such time as the entire appendix is reissued.

Reporting parties should note that several conditions reportable or under surveillance in Mississippi are not contained in this appendix. If there are questions or concerns about these conditions the Office of Epidemiology is available to answer questions.

Two additional definitions included at the end of the appendix are not part of the CSTE/CDC list. The Surveillance Branch of the Bureau of Emergency Medical Services conducts surveillance for spinal cord and traumatic brain injuries. The definitions used by this program are presented as adopted by the National Center for Injury Control and Prevention at CDC and participating states.

Clinicians should note that these definitions are specifically for surveillance purposes and should not be used for diagnosis, or replace or substitute for sound clinical judgment.

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Definition of Terms Used in Case Classification

Clinically Compatible Case: A clinical syndrome generally compatible with the disease, for which no specific clinical criteria need to be met except for those noted in the case classification.

Confirmed Case: A case that is classified as confirmed for reporting purposes. Cases reported with this status will be printed in the *MMWR* notifiable disease tables.

Epidemiologically Linked Case: A case in which the patient has had contact with one or more persons who have/had the disease, and transmission of the agent by the usual modes of transmission is plausible. A case may be considered epidemiologically linked to a laboratory confirmed case if at lease one case in the chain of transmission is laboratory confirmed.

Laboratory-confirmed Case: A case that is confirmed by one or more of the laboratory methods listed in the case definition under "Laboratory criteria for diagnosis." Although other laboratory methods may be used in clinical diagnosis, only those listed are accepted for laboratory confirmation for reporting purposes.

Probable Case: A case that is classified as probable for reporting purposes. Except where noted in the case definition, cases reported with this status will be printed in the *MMWR* notifiable disease tables.

Supportive Laboratory Results: Specified laboratory results consistent with the diagnosis but not meeting the criteria for laboratory confirmation.

Suspected Case: A case that is classified as suspected for reporting purposes. Suspect cases will not be printed in the *MMWR* notifiable disease tables.

Acquired Immunodeficiency Syndrome (AIDS) and HIV (Revised 12/10/99) *

Case definition

This revised definition of HIV infection, which applies to any HIV (e.g., HIV-1 or HIV-2), is intended for public health surveillance only. It incorporates the reporting criteria for HIV infection and AIDS into a single case definition. The revised criteria for HIV infection update the definition of HIV infection implemented in 1993; the revised HIV criteria apply to AIDS-defining conditions for adults and children, which require laboratory evidence of HIV.

I. In adults, adolescents, or children aged greater than or equal to 18 months**, a reportable case of HIV infection must meet at least one of the following criteria:

Laboratory criteria

- Positive result on a screening test for HIV antibody (e.g., repeatedly reactive enzyme mmunoassay), followed by a positive result on a confirmatory (sensitive and more pecific) test for HIV antibody (e.g., Western blot or immunofluorescence antibodytest) or
- Positive results or report of a detectable quantity on any of the following HIV virologic nonantibody) tests:
 - 1. HIV nucleic acid (DNA or RNA) detection (e.g., DNA polymerase chain reaction [PCR] or plasma HIV-1 RNA)***
 - 2. HIV p24 antigen test, including neutralization assay
 - 3. HIV isolation (viral culture)

OR

Clinical or other criteria (if the above laboratory criteria are not met)

- Diagnosis of HIV infection, based on the laboratory criteria above, that is documented in a medical record by a physician, or
- Conditions that meet criteria included in the case definition for AIDS, or

^{*} Draft revised surveillance criteria for HIV infection were approved and recommended by the membership of the Council of State and Territorial Epidemiologists (CSTE) at the 1998 annual meeting (11). Draft versions of these criteria were previously reviewed by state HIV/AIDS surveillance staffs, CDC, CSTE, and laboratory experts. In addition, the pediatric criteria were reviewed by an expert panel of consultants. [External Pediatric Consultants: C. Hanson, M. Kaiser, S. Paul, G. Scott, and P. Thomas. CDC staff: J. Bertolli, K. Dominguez, M. Kalish, M.L. Lindegren, M. Rogers, C. Schable, R.J. Simonds, and J. Ward]

^{**} Children aged ≥18 months but less than 13 years are categorized as not infected with HIV if they meet the criteria in III.

^{***} In adults, adolescents, and children infected by other than perinatal exposure, plasma viral RNA nucleic acid tests should **NOT** be used in lieu of licensed HIV screening tests (e.g., repeatedly reactive enzyme immunoassay). In addition, a negative (i.e.,undetectable) plasma HIV-1 RNA test result does not rule out the diagnosis of HIVinfection.

- At least two negative HIV virologic tests from separate specimens, both of which were performed at greater than or equal to 1 month of age and one of which was performed greater than or equal to 4 months of age, and
- No other laboratory or clinical evidence of HIV infection (i.e., has not had any positive virologic tests, if performed, and has not had an AIDS-defining condition, or

Presumptive: a child who does not meet the above criteria for definitive "not infected" status, but who has:

- One negative EIA HIV antibody test performed at greater than or equal to 6 months of age and NO positive HIV virologic tests, if performed, or
- One negative HIV virologic test performed at greater than or equal to 4 months of age and NO positive HIV virologic tests, if performed,
- One positive HIV virologic test with at least two subsequent negative virologic tests^{*}, at least one of which is at greater than or equal to 4 months of age; or negative HIV antibody test results, at least one of which is greater than or equal to 6months of age, and no other laboratory or clinical evidence of HIV infection (i.e., has not had any positive virologic tests, if performed, and has not had an AIDS-defining condition).

OR

Clinical or other criteria (if the above definitive or presumptive laboratory criteria are not met)

- Determined by a physician to be "not infected", and a physician has noted the results of the preceding HIV diagnostic tests in the medical record, and
- NO other laboratory or clinical evidence of HIV infection (i.e., has not had any positive virologic tests, if performed, and has not had an AIDS-defining condition)

II. In a child aged less than 18 months, a reportable case of HIV infection must meet at least one of the following criteria:

Laboratory criteria

Definitive

- Positive results on two separate specimens (excluding cord blood) using one or moreof the following HIV virologic (nonantibody) tests:
 - 1. HIV nucleic acid (DNA or RNA) detection
 - 2. HIV p24 antigen test, including neutralization assay, in a child ≥to 1 month of age
 - 3. HIV isolation (viral culture), or

^{*} HIV nucleic acid (DNA or RNA) detection tests are the virologic methods of choice to exclude infection in children aged less than 18 months. Although HIV culture can be used for this purpose, it is more complex and expensive to perform and is less well standardized than nucleic acid detection tests. The use of p24 antigen testing to exclude infection in children aged <18 months is not recommended because of its lack of sensitivity.

Presumptive: a child who does not meet the criteria for definitive HIV infection but who has:

• Positive results on only one specimen (excluding cord blood) using the above HIV virologic tests and no subsequent negative HIV virologic or negative HIV antibody tests

OR

Clinical or other Criteria (if the above definitive or presumptive laboratory criteria are not met)

- Diagnosis of HIV infection, based on the laboratory criteria above, that is documented in a medical record by a physician, or
- Conditions that meet criteria included in the 1987 pediatric surveillance case definition for AIDS
- III. A child aged less than 18 months born to an HIV infected mother will be categorized for surveillance purposes as "not infected with HIV" if the child does not meet the criteria for HIV infection but meets the following criteria:

Laboratory criteria

Definitive: At least two negative HIV antibody tests from separate specimens obtained at greater than or equal to 6 months of age

IV. A child aged less than 18 months born to an HIV-infected mother will be categorized as having perinatal exposure to HIV infection if the child does not meet the criteria for HIV infection (II) or the criteria for "not infected with HIV" (III).

Anthrax (Revised 9/96)

Clinical description

An illness with acute onset characterized by several distinct clinical forms including:

- **Cutaneous**: a skin lesion evolving over 2 to 6 days from a papule, through a vesicular stage, to a depressed black eschar
- **Inhalation**: a brief prodrome resembling a viral respiratory illness followed by development of hypoxia and dyspnea, with x-ray evidence of mediastinal widening
- **Intestinal**: severe abdominal distress followed by fever and signs of septicemia)
- **Oropharyngeal**: mucosal lesion in the oral cavity or oropharynx, cervical adenopathy and edema, and fever

Laboratory criteria for diagnosis

- Isolation of *Bacillus anthracis* from a clinical specimen, or
- Anthrax electrophoretic immunotransblot (EITB) reaction to the protective antigen and/or lethal factor bands in one or more serum samples obtained after onset of symptoms, or
- Demonstration of *B. anthracis* in a clinical specimen by immunofluorescence

Case classification

Confirmed: a clinically compatible case that is laboratory confirmed.

Aseptic Meningitis

Clinical description

A syndrome characterized by acute onset of meningeal symptoms, fever, and cerebrospinal fluid pleocytosis, with bacteriologically sterile cultures.

Laboratory criteria for diagnosis

No evidence of bacterial or fungal meningitis

Case classification

Confirmed: a clinically compatible case diagnosed by a physician as aseptic meningitis, with no laboratory evidence of bacterial or fungal meningitis.

Comment

Aseptic meningitis is a syndrome of multiple etiologies, but many cases are caused by a viral agent.

Bacterial Meningitis, Other (Adopted 9/96)

Clinical description

Bacterial meningitis manifests most commonly with fever, headache, and a stiff neck, which may progress rapidly to shock and death. However, other manifestations may be observed.

Laboratory criteria for diagnosis

• Isolation of a bacterial species from the cerebrospinal fluid

Case classification

Confirmed: A clinically compatible case that is laboratory confirmed.

Comment

Cases of bacterial meningitis caused by *Haemophilus influenzae*, *Neisseria meningitidis*, group A *streptococcus*, and *Listeria monocytogenes* should be reported to NNDSS under the disease codes specific for these organisms. Only cases of bacterial meningitis due to other organisms should be reported as cases of "bacterial meningitis, other".

Botulism, Foodborne (Revised 9/96)

Clinical description

Ingestion of botulinal toxin results in an illness of variable severity. Common symptoms are diplopia, blurred vision, and bulbar weakness. Symmetric paralysis may progress rapidly.

Laboratory criteria for diagnosis

- Detection of botulinal toxin in serum, stool, or patient's food or
- Isolation of *Clostridium botulinum* from stool

Case classification

Probable: a clinically compatible case with an epidemiologic link (e.g., ingestion of a homecanned food within the previous 48 hours)

Confirmed: a clinically compatible case that is laboratory confirmed or that occurs among persons who ate the same food as persons with laboratory-confirmed botulism

Botulism, Infant (Revised 9/96)

Clinical description

An illness of infants, characterized by constipation, poor feeding, and "failure to thrive" that may be followed by progressive weakness, impaired respiration, and death

Laboratory criteria for diagnosis

- Detection of botulinal toxin in stool, or
- Isolation of Clostridium botulinum from stool

Case classification

Confirmed: a clinically compatible case that is laboratory-confirmed, occurring in a child aged <1 year

Botulism, Wound

Clinical description

An illness resulting from toxin produced by *Clostridium botulinum* that has infected a wound. Common symptoms are diplopia, blurred vision, and bulbar weakness. Symmetric paralysis may progress rapidly.

Laboratory criteria for diagnosis

- Detection of botulinal toxin in serum, or
- Isolation of *C. botulinu*m from wound

Case classification

Confirmed: a clinically compatible case that is laboratory confirmed in a patient who has no suspected food exposure to contaminated food and who has a history of a fresh, contaminated wound during the 2 weeks before onset of symptoms.

Botulism, Other

Clinical description

See Foodborne Botulism.

Laboratory criteria for diagnosis

- Detection of botulinal toxin in clinical specimen, or
- Isolation of *Clostridium botulinum* from clinical specimen

Case classification

Confirmed: a clinically compatible case that is laboratory confirmed in a patient aged ≥ 1 year who has no history of ingestion of suspect food and has no wounds

Brucellosis

Clinical description

An illness characterized by acute or insidious onset of fever, night sweats, undue fatigue, anorexia, weight loss, headache, and arthralgia

Laboratory criteria for diagnosis

- Isolation of *Brucella* sp. from a clinical specimen, or
- Fourfold or greater rise in *Brucella* agglutination titer between acute- and convalescent-phase serum specimens obtained ≥ 2 weeks apart and studied at the same laboratory, or
- Demonstration by immunofluorescence of *Brucella* sp. in a clinical specimen

Case classification

Probable: a clinically compatible case that is epidemiologically linked to a confirmed case or that has supportive serology. (i.e., *Brucella* agglutination titer of ≥ 160 in one or more serum specimens obtained after onset of symptoms)

Confirmed: a clinically compatible case that is laboratory confirmed

Campylobacter Infection

Clinical description

An infection that may result in diarrheal illness of variable severity.

Laboratory criteria for diagnosis

• Isolation of *Campylobacter* from any clinical specimen

Case classification

Probable: A clinically compatible case that is epidemiologically linked to a confirmed case.

Confirmed: A case that is laboratory confirmed.

Comment

Only confirmed cases are reported to the laboratory-based surveillance system operated by the National Center for Infectious Diseases, Foodborne and Diarrheal Diseases Branch.

Chancroid (Revised 9/96)

Clinical description

A sexually transmitted disease characterized by painful genital ulceration and inflammatory inguinal adenopathy. The disease is caused by infection with *Haemophilus ducreyi*.

Laboratory criteria for diagnosis

• Isolation of *H. ducreyi* from a clinical specimen

Case classification

Probable: a clinically compatible case with both (a) no evidence of *Treponema pallidum* infection by darkfield examination of ulcer exudate or by a serologic test for syphilis performed ≥ 7 days after onset of ulcers, and (b) the clinical presentation of the ulcer(s) is not typical of disease caused by herpes simplex virus (HSV), or HSV culture is negative.

Confirmed: a clinically compatible case that is laboratory confirmed

Chlamydia trachomatis, Genital infections (Revised 9/96)

Clinical description

Infection with *Chlamydia trachomatis* may result in urethritis, epididymitis, cervicitis, acute salpingitis, or other syndromes when sexually transmitted, however the infection often asymptomatic in women. Perinatal infections may result in inclusion conjunctivitis and pneumonia in newborns. Other syndromes caused by *C. trachomatis* include lymphogranuloma venereum and trachoma.

Laboratory criteria for diagnosis

- Isolation of *C. trachomatis* by culture or
- Demonstration of *C. trachomatis* in a clinical specimen by detection of antigen or nucleic acid

Case classification

Confirmed: a case that is laboratory confirmed

Cholera (Revised 9/96)

Clinical description

An illness characterized by diarrhea and/or vomiting; severity is variable.

Laboratory criteria for diagnosis

- Isolation of toxigenic (i.e., cholera toxin-producing) *Vibrio cholerae* O1 or O139 from stool or vomitus, or
- Serologic evidence of recent infection

Case classification

Confirmed: a clinically compatible case that is laboratory confirmed

Comment

Illnesses caused by strains of *V. cholerae* other than toxigenic *V. cholerae* O1 or O139 should not be reported as cases of cholera. The etiologic agent of a case of cholera should be reported as either *V. cholerae* O1 or *V. cholerae* O139. Only confirmed cases should be reported to the NNDSS by state health departments.

Cryptosporidiosis (Revised 5/98)

Clinical description

An illness caused by the protozoan *Cryptosporidium parvum* and characterized by diarrhea, abdominal cramps, loss of appetite, low-grade fever, nausea, and vomiting. Infected persons may be asymptomatic. The disease can be prolonged and life-threatening in severely immunocompromised persons.

Laboratory criteria for diagnosis

Laboratory confirmed cryptosporidiosis shall be defined as the detection in symptomatic or asymptomatic persons of *Cryptosporidiosis*

- Oocysts in stool by microscopic examination, or
- In intestinal fluid or small-bowel biopsy specimens, or
- Oocysts or sporozoite antigens by immunodiagnostic methods, e.g., ELISA, or
- By PCR techniques when routinely available, or

• Demonstrations of reproductive stages in tissue preparations.

Case classification

Confirmed, symptomatic: a laboratory-confirmed case associated with one of the symptoms described above

Confirmed, asymptomatic: a laboratory confirmed-case associated with none of the above symptoms

Dengue Fever (revised 1996)

Clinical description

An acute febrile illness characterized by frontal headache, retro-ocular pain, muscle and joint pain, and rash. The vector is the *Aedes aegypti* mosquito and transmission usually occurs in tropical and subtropical areas. Severe manifestations (i.e., dengue hemorrhagic fever and dengue shock syndrome) are rare, but may be fatal.

Laboratory criteria for diagnosis (confirmation)

- Isolation of dengue virus from serum and/or autopsy tissue samples, or
- Demonstration of a fourfold or greater rise or fall in reciprocal immunoglobulin G (IgG) or immunoglobulin M (IgM) antibody titers to one or more dengue virus antigens in paired serum samples, or
- Demonstration of dengue virus antigen in autopsy tissue or serum samples by immunohistochemistry or by viral nucleic acid detection.

Case classification

Probable: a clinically compatible case with supportive serology (a reciprocal IgG antibody titer of \geq 1280 or a positive IgM antibody test on a single acute (late) or convalescent-phase serum specimen to one or more dengue virus antigens).

Confirmed: A clinically compatible case that is laboratory confirmed.

Comment

Dengue hemorrhagic fever is defined as an acute febrile illness with minor or major bleeding phenomena, thrombocytopenia ($\leq 100,000/\text{mm}$ 3), and evidence of plasma leakage documented by hemoconcentration (hematocrit increased by $\geq 20\%$) or other objective evidence of increased capillary permeability. The definition of dengue shock syndrome follows all of the above criteria for dengue hemorrhagic fever and also includes hypotension or narrow pulse pressure ($\leq 20 \text{ mm Hg}$).

Diphtheria (Revised 3/95)

Clinical description

An upper respiratory tract illness characterized by sore throat, low grade fever, and an adherent membrane of the tonsil(s), pharynx, and/or nose

Laboratory criteria for diagnosis

- Isolation of Corynebacterium diphtheriae from a clinical specimen or
- Histopathologic diagnosis of diphtheria

Case classification

Probable: a clinically compatible case that is not laboratory confirmed and is not epidemiologically linked to a laboratory-confirmed case

Confirmed: A clinically compatible case that is laboratory confirmed or epidemiologically linked to a laboratory confirmed case

Comment

Cutaneous diphtheria should not be reported. Respiratory disease caused by nontoxigenic *C. diphtheriae* should be reported as diphtheria. All diphtheria isolates, whether associated with disease or not, should be sent to the National Center for Infectious Diseases, CDC.

Ehrlichiosis/Anaplasmosis (Revised 2008)

Clinical presentation

A tick-borne illness characterized by acute onset of fever and one or more of the following symptoms or signs: headache, myalgia, malaise, anemia, leukopenia, thrombocytopenia, or elevated hepatic transaminases. Nausea, vomiting, or rash may be present in some cases. Intracytoplasmic bacterial aggregates (morulae) may be visible in the leukocytes of some patients.

Clinical evidence

Any reported fever and one or more of the following: headache, myalgia, anemia, leukopenia, thrombocytopenia, or any hepatic transaminase elevation.

Laboratory evidence

For the purposes of surveillance,

1. *Ehrlichia chaffeensis* infection (formerly included in the category Human Monocytic Ehrlichiosis[HME]):

Laboratory confirmed:

- Serological evidence of a fourfold change in immunoglobulin G (IgG)-specific antibody titer to *E. chaffeensis* antigen by indirect immunofluorescence assay (IFA) between paired serum samples (one taken in first week of illness and a second 2-4 weeks later), **or**
- Detection of *E. chaffeensis* DNA in a clinical specimen via amplification of a specific target by polymerase chain reaction (PCR) assay, **or**
- Demonstration of ehrlichial antigen in a biopsy or autopsy sample by immunohistochemical methods, or
- Isolation of *E. chaffeensis* from a clinical specimen in cell culture.

Laboratory supportive:

- Serological evidence of elevated IgG or IgM antibody reactive with *E. chaffeensis* antigen by IFA, enzyme-linked immunosorbent assay (ELISA), dot-ELISA, or assays in other formats (CDC uses an IFA IgG cutoff of ≥1:64 and does not use IgM test results independently as diagnostic support criteria.), **or**
- Identification of morulae in the cytoplasm of monocytes or macrophages by microscopic examination.
- 2. *Ehrlichia ewingii* infection (formerly included in the category Ehrlichiosis [unspecified, or other agent]):

Laboratory confirmed:

- Because the organism has never been cultured, antigens are not available. Thus, *Ehrlichia ewingii* infections may only be diagnosed by molecular detection methods: *E. ewingii* DNA detected in a clinical specimen via amplification of a specific target by polymerase chain reaction (PCR) assay.
- 3. *Anaplasma phagocytophilum* infection (formerly included in the category Human Granulocytic Ehrlichiosis [HGE]):

Laboratory confirmed:

- Serological evidence of a fourfold change in IgG-specific antibody titer to *A. phagocytophilum* antigen by indirect immunofluorescence assay (IFA) in paired serum samples (one taken in first week of illness and a second 2-4 weeks later), or
- Detection of *A. phagocytophilum* DNA in a clinical specimen via amplification of a specific target by polymerase chain reaction (PCR) assay, **or**
- Demonstration of anaplasmal antigen in a biopsy/autopsy sample by immunohistochemical methods, **or**
- Isolation of A. phagocytophilum from a clinical specimen in cell culture.

Laboratory supportive:

- Serological evidence of elevated IgG or IgM antibody reactive with A. phagocytophilum antigen by IFA, enzyme-linked immunosorbent Assay (ELISA), dot-ELISA, or assays in other formats (CDC uses an IFA IgG cutoff of ≥1:64 and does not use IgM test results independently as diagnostic support criteria.), or
- Identification of morulae in the cytoplasm of neutrophils or eosinophils by microscopic examination.

4. Human ehrlichiosis/anaplasmosis – undetermined:

• See case classification

Exposure

Exposure is defined as having been in potential tick habitats within the past 14 days before onset of symptoms. A history of a tick bite is not required.

Case Classification

Confirmed: A clinically compatible case (meets clinical evidence criteria) that is laboratory confirmed.

Probable: A clinically compatible case (meets clinical evidence criteria) that has supportive laboratory results. For ehrlichiosis/anaplasmosis – an undetermined case can only be classified as probable. This occurs when a case has compatible clinical criteria with laboratory evidence to support ehrlichia/anaplasma infection, but not with sufficient clarity to definitively place it in one of the categories previously described. This may include the identification of morulae in white cells by microscopic examination in the absence of other supportive laboratory results.

Suspect: A case with laboratory evidence of past or present infection but no clinical information available (e.g. a laboratory report).

Comment

There are at least three species of bacteria, all intracellular, responsible for ehrlichiosis/ anaplasmosis in the United States: *Ehrlichia chaffeensis*, found primarily in monocytes, and *Anaplasma phagocytophilum* and *Ehrlichia ewingii*, found primarily in granulocytes. The clinical signs of disease that result from infection with these agents are similar, and the range distributions of the agents overlap, so testing for one or more species may be indicated. Serologic cross-reactions may occur among tests for these etiologic agents.

Four sub-categories of confirmed or probable ehrlichiosis/anaplasmosis should be reported: 1) human ehrlichiosis caused by *Ehrlichia chaffeensis*, 2) human ehrlichiosis caused by *E. ewingii*, 3) human anaplasmosis caused by *Anaplasma phagocytophilum*, or 4) human ehrlichiosis/anaplasmosis - undetermined. Cases reported in the fourth sub-category can only be reported as "probable" because the cases are only weakly supported by ambiguous laboratory test results.

Problem cases for which sera demonstrate elevated antibody IFA responses to more than a single infectious agent are usually resolvable by comparing the levels of the antibody responses, the greater antibody response generally being that directed at the actual agent involved. Tests of additional sera and further evaluation via the use of PCR, IHC, and isolation via cell culture may be needed for further clarification. Cases involving persons infected with more than a single etiologic agent, while possible, are extremely rare and every effort should be undertaken to resolve cases that appear as such (equivalent IFA antibody titers) via other explanations.

Current commercially available ELISA tests are not quantitative, cannot be used to evaluate changes in antibody titer, and hence are not useful for serological confirmation. Furthermore, IgM tests are not always specific and the IgM response may be persistent. Therefore, IgM tests are not strongly supported for use in serodiagnosis of acute disease.

Encephalitis, Arboviral (Revised 2004)

Neuroinvasive and Non-Neuroinvasive Domestic Arboviral Diseases(includes diseases caused by California serogroup viruses; eastern and western equine encephalitis viruses; and Powassan, St. Louis encephalitis, and West Nile viruses)

Clinical criteria for diagnosis

Cases of arboviral disease are classified either as neuroinvasive or non-neuroinvasive, according to the following criteria:

Neuroinvasive disease requires the presence of fever and at least one of the following, as documented by a physician and in the absence of a more likely clinical explanation:

- 1. Acutely altered mental status (e.g., disorientation, obtundation, stupor, or coma), or
- 2. Other acute signs of central or peripheral neurologic dysfunction (e.g., paresis or paralysis, nerve palsies, sensory deficits, abnormal reflexes, generalized convulsions, or abnormal movements), or
- 3. Pleocytosis (increased white blood cell concentration in cerebrospinal fluid [CSF]) associated with illness clinically compatible with meningitis (e.g., headache or stiff neck).

Non-neuroinvasive disease requires, at minimum, the presence of documented fever, as measured by the patient or clinician, the absence of neuroinvasive disease (above), and the absence of a more likely clinical explanation for the illness. Involvement of non-neurological organs (e.g., heart, pancreas, liver) should be documented using standard clinical and laboratory criteria.

Laboratory criteria for diagnosis

Cases of arboviral disease are also classified either as confirmed or probable, according to the following laboratory criteria:

Confirmed case:

Four-fold or greater change in virus-specific serum antibody titer, or

Isolation of virus from or demonstration of specific viral antigen or genomic sequences in tissue, blood, CSF, or other body fluid, or

Virus-specific immunoglobulin M (IgM) antibodies demonstrated in CSF by antibody-capture enzyme immunoassay (EIA), or

Virus-specific IgM antibodies demonstrated in serum by antibody-capture EIA and confirmed by demonstration of virus-specific serum immunoglobulin G (IgG) antibodies in the same or a later specimen by another serologic assay (e.g., neutralization or hemagglutination inhibition).

Probable case:

Stable (less than or equal to a two-fold change) but elevated titer of virus-specific serum antibodies, or

Virus-specific serum IgM antibodies detected by antibody-capture EIA but with no available results of a confirmatory test for virus-specific serum IgG antibodies in the same or a later specimen.

Case definition

A case must meet one or more of the above clinical criteria and one or more of the above laboratory criteria.

Comment

Because closely related arboviruses exhibit serologic cross-reactivity, positive results of serologic tests using antigens from a single arbovirus can be misleading. In some circumstances (e.g., in areas where two or more closely related arboviruses occur, or in imported arboviral disease cases), it may be epidemiologically important to attempt to pinpoint the infecting virus by conducting cross-neutralization tests using an appropriate battery of closely related viruses. This is essential, for example, in determining that antibodies detected against St. Louis encephalitis virus are not the result of an infection with West Nile (or dengue) virus, or vice versa, in areas where both of these viruses occur. Because dengue fever and West Nile fever can be clinically indistinguishable, the importance of a recent travel history and appropriate serologic testing cannot be overemphasized. In some persons, West Nile virus-specific serum IgM antibody can wane slowly and be detectable for more than one year following infection. Therefore, in areas where West Nile virus has circulated in the recent past, the co-existence of West Nile virus-specific IgM antibody and illness in a given case may be coincidental and unrelated. In those areas, the testing of serially collected serum specimens assumes added importance.

The seasonality of arboviral transmission is variable and depends on the geographic location of exposure, the specific cycles of viral transmission, and local climatic conditions. Reporting should be etiology-specific (see below; the six diseases printed in bold are nationally reportable to CDC):

St. Louis encephalitis virus disease West Nile virus disease Powassan virus disease Eastern equine encephalitis virus disease Western equine encephalitis virus disease

California serogroup virus disease (includes infections with the following viruses: California encephalitis, Jamestown Canyon, Keystone, La Crosse, snowshoe hare, and trivittatus)

Note: Due to the continued risk of unintentional or intentional introduction of exotic arboviruses into the United States (e.g., Venezuelan equine encephalitis virus), or the reemergence of indigenous epidemic arboviruses (e.g., St. Louis encephalitis and western equine encephalitis viruses), physicians and local public health officials should maintain a high index of clinical suspicion for cases of potential exotic or unusual arboviral etiology, and consider early consultation with arboviral disease experts at state health departments and CDC.

Escherichia coli O157:H7 (Revised 12/00)

Clinical description

An infection of variable severity characterized by diarrhea (often bloody) and abdominal cramps. Illness may be complicated by hemolytic uremic syndrome (HUS) or thrombotic thrombocytopenic purpura (TTP); asymptomatic infections may also occur.

Laboratory criteria for diagnosis

- Isolation of *E. coli* O157:H7 from a specimen, or
- Isolation of Shiga toxin-producing E. coli O157:NM from a clinical specimen*

Case classification

Suspected: A case of post-diarrheal HUS or TTP (see HUS case definition)

Probable:

- Isolation of *E. coli* O157 from a clinical specimen, pending confirmation of H7 or Shiga toxin, or
- A clinically compatible case that is epidemiologically linked to a confirmed or probable case, or
- A clinically compatible case that is epidemiologically linked to a confirmed or probable case or
- Identification of Shiga toxin in a specimen from a clinically compatible case, or
- Definitive evidence of an elevated antibody titer to a known EHEC serotype from a clinically compatible case

Confirmed: A case that meets the laboratory criteria for diagnosis.

Comment

Laboratory-confirmed isolates are reported via the Public Health Laboratory Information System (PHLIS), which is managed by the Foodborne and Diarrheal Diseases Branch, Division of Bacterial and Mycotic Diseases, National Center for Infectious Diseases, CDC. Both probable and confirmed cases are reported to the National Notifiable Diseases Surveillance System (NNDSS), but only confirmed cases are reported to PHLIS. Confirmation is based on laboratory findings, and clinical illness is not required.

Gonorrhea (Revised 9/96)Clinical description

A sexually transmitted infection commonly manifested by urethritis, cervicitis, or salpingitis. Infection may be asymptomatic.

* Strains of E.coli 0157:H7 that have lost the flagellar "H" antigen become nonmotile and are designated "NM".

Laboratory criteria for diagnosis

- Isolation of typical gram-negative, oxidase-positive diplococci (presumptive *Neisseria gonorrhoeae*) from a clinical specimen, or
- Demonstration of *N. gonorrhoeae* in a clinical specimen by detection of antigen or nucleic acid, or
- Observation of gram-negative intracellular diplococci in a urethral smear obtained from a male

Case classification

Probable: a) demonstration of gram-negative intracellular diplococci in an endocervical smear obtained from a woman, or b) a written morbidity report of gonorrhea submitted by a physician

Confirmed: a case that is laboratory confirmed

Haemophilus influenzae (Invasive Disease)

Clinical description

Invasive disease due to *Haemophilus influenzae* may produce any of several clinical syndromes, including meningitis, bacteremia, epiglottitis, or pneumonia.

Laboratory criteria for diagnosis

• Isolation of H. influenzae from a normally sterile site (e.g., blood or cerebrospinal fluid (CSF), or, less commonly, joint, pleural, or pericardial fluid)

Case classification

Probable: a clinically compatible case with detection of *H. influenzae* type b antigen in CSF

Confirmed: a clinically compatible case that is culture confirmed

Comment

Positive antigen test results from urine or serum are unreliable for diagnosis of *H. influenzae* disease.

Hansen Disease (Leprosy)

Clinical description

A chronic bacterial disease characterized by the involvement primarily of mainly skin as well as peripheral nerves and the mucosa of the upper airway. Clinical forms of Hansen disease represent a spectrum reflecting the cellular immune response to *Mycobacterium leprae*. Typical of the major forms of the disease are the following characteristics:

• *Tuberculoid*: one or a few well-demarcated, hypopigmented, and anesthetic skin lesions, frequently with active, spreading edges and a clearing center; peripheral nerve swelling or thickening may also occur

- Lepromatous: a number of erythematous papules and nodules or an infiltration of the face, hands, and feet with lesions in a bilateral and symmetrical distribution that progress to thickening of the skin
- Borderline (dimorphous): skin lesions characteristic of both the tuberculoid and lepromatous forms
- *Indeterminate*: early lesions, usually hypopigmented macules, without developed tuberculoid or lepromatous features

Laboratory criteria for diagnosis

• Demonstration of acid-fast bacilli in skin or dermal nerve, obtained from the full-thickness skin biopsy of a lepromatous lesion

Case classification

Confirmed: a clinically compatible case that is laboratory confirmed.

Hemolytic Uremic Syndrome, Postdiarrheal (Revised 9/96)

Clinical description

Hemolytic uremic syndrome (HUS) is characterized by the acute onset of microangiopathic hemolytic anemia, renal injury, and low platelet count. Thrombotic thrombocytopenic purpura (TTP) is also characterized by these features but also can include central nervous system (CNS) involvement and fever, and may have a more gradual onset. Most cases of HUS (but few cases of TTP) occur after an acute gastrointestinal illness (usually diarrheal).

Laboratory criteria for diagnosis

The following are both present at some time during the illness:

- Anemia (acute onset) with microangiopathic changes (i.e., schistocytes, burr cells, or helmet cells) on peripheral blood smear and
- Renal injury (acute onset), evidenced by either hematuria, proteinuria, or elevated creatinine level (i.e., ≥ 1.0 mg/dL in a child <13 years of age or ≥ 1.5 mg/dL in an adult, or ≥ 50% increase over baseline)

Note: A low platelet count can usually, but not always, be detected early in the illness, but it may then become normal or even high. If a platelet count obtained within 7 days after onset of the acute gastrointestinal illness is not <150,000/mm³, other diagnoses should be considered.

Case classification

Probable:

- An acute illness diagnosed as HUS or TTP that meets the laboratory criteria in a patient who does not have a clear history of acute or bloody diarrhea in preceding 3 weeks, or
- An acute illness diagnosed as HUS or TTP, that a) has an onset within 3 weeks after onset of an acute or bloody diarrhea and b) meets the laboratory criteria except that microangiopathic changes are not confirmed

Confirmed: an acute illness diagnosed as HUS or TTP that meets the laboratory criteria and began within 3 weeks after onset of an episode of acute or bloody diarrhea

Comment

Some investigators consider HUS and TTP to be part of a continuum of disease. Therefore, criteria for diagnosing TTP on the basis of CNS involvement and fever are not provided because cases diagnosed clinically as postdiarrheal TTP also should meet the criteria for HUS. These cases are reported as postdiarrheal HUS.

Hepatitis A, Acute (Revised 2000)

Clinical case definition

An acute illness with a) discrete onset of symptoms and b) jaundice or elevated serum aminotransferase levels

Laboratory criteria for diagnosis:

Immunoglobulin M (IgM) antibody to hepatitis A virus (anti-HAV) positive

Case classification

Confirmed: a case that meets the clinical case definition and is laboratory confirmed

or

a case that meets the clinical case definition and occurs in a person who has an epidemiologic link with a person who has laboratory-confirmed hepatitis A (i.e., household or sexual contact with an infected person during the 15-50 days before the onset of symptoms)

Hepatitis B, Acute (Revised 2000)

Clinical case definition

An acute illness with a) discrete onset of symptoms **and** b) jaundice or elevated serum aminotransferase levels

Laboratory criteria for diagnosis:

IgM antibody to hepatitis B core antigen (anti-HBc) positive or hepatitis B surface antigen (HBsAg) positive and IgM anti-HAV negative (if done)

Case classification

Confirmed: a case that meets the clinical case definition and is laboratory confirmed

Hepatitis, Viral, Perinatal Hepatitis B Virus Infection Acquired in the United States or U.S. Territories

1995 Case Definition

The 1995 case definition appearing on this page was re-published incorrectly in the 1997 MMWR Recommendations and Reports titled *Case Definitions for Infectious Conditions Under Public Health Surveillance* [MMWR 1997;46(RR10)] (available at http://www.cdc.gov/mmwr/preview/mmwrhtml/00047449.htm). Thus, the 1995 and the 1997 versions of this case definition are not identical, and the 1995 version is the correct one.

Clinical case definition

Perinatal hepatitis B in the newborn may range from asymptomatic to fulminant hepatitis.

Laboratory criteria for diagnosis:

• Hepatitis B surface antigen (HBsAg) positive

Case classification

HBsAg positivity in any infant aged >1-24 months who was born in the United States or in U.S. territories to an HBsAg-positive mother

Comment

Infants born to HBsAg-positive mothers should receive hepatitis B immune globulin (HBIG) and the first dose of hepatitis B vaccine within 12 hours of birth, followed by the second and third doses of vaccine at 1 and 6 months of age, respectively. Postvaccination testing for HBsAg and anti-HBs (antibody to HBsAg) is recommended from 3 to 6 months following completion of the vaccine series. If HBIG and the initial dose of vaccine are delayed for >1 month after birth, testing for HBsAg may determine if the infant is already infected.

Hepatitis C virus infection, acute (Revised 2007)

Clinical case definition

An acute illness with a discrete onset of any sign or symptom consistent with acute viral hepatitis (e.g., anorexia, abdominal discomfort, nausea, vomiting), and either a) jaundice, or b) serum alanine aminotransferase (ALT) levels >400 IU/L.

Laboratory criteria for diagnosis

One or more of the following three criteria:

- 1. Antibodies to hepatitis C virus (anti-HCV) screening-test-positive with a signal to cut-off ratio predictive of a true positive as determined for the particular assay as defined by CDC. (URL for the signal to cut-off ratios:
 - http://www.cdc.gov/ncidod/diseases/hepatitis/c/sc ratios.htm) OR

- 2. Hepatitis C Virus Recombinant Immunoblot Assay (HCV RIBA) positive, **OR**
- 3. Nucleic Acid Test (NAT) for HCV RNA positive

AND, meets the following two criteria:

- 1. IgM antibody to hepatitis A virus (IgM anti-HAV) negative, AND
- 2. IgM antibody to hepatitis B core antigen (IgM anti-HBc) negative

Case classification:

Confirmed: a case that meets the clinical case definition, is laboratory confirmed, and is not known to have chronic hepatitis C.

Influenza-Associated Pediatric Mortality (Adopted 2/08)

Case Definition

A pediatric influenza-associated death is defined for surveillance purposes as a death resulting from a clinically compatible illness that was confirmed to be influenza by an appropriate laboratory or rapid diagnostic test in a person aged <18 years.

A death should not be reported if:

- 1. There is no laboratory confirmation of influenza virus infection.
- 2. The influenza illness is followed by full recovery to baseline health status prior to death.
- 3. The death occurs in a person 18 years or older.
- 4. After review and consultation there is an alternative agreed upon cause of death.

Laboratory criteria for diagnosis

Laboratory testing for influenza virus infection may be done on pre- or post-mortem clinical specimens, and include identification of influenza A or B virus infections by a positive result by at least one of the following:

- Influenza virus isolation in tissue cell culture from respiratory specimens;
- Reverse-transcriptase polymerase chain reaction (RT-PCR) testing of respiratory specimens;
- Direct or indirect immunofluorescent antibody staining of respiratory specimens;
- Rapid influenza diagnostic testing of respiratory specimens;
- Immunohistochemical (IHC) staining for influenza viral antigens in respiratory tract tissue from autopsy specimens;

• Four-fold rise in influenza hemagglutination inhibition (HI) antibody titer in paired acute and convalescent sera*.

Case classification

Confirmed - A death meeting the clinical case definition that is laboratory confirmed.

Laboratory confirmation is required as part of the case definition; therefore, all deaths reported in the MMWR will be classified as confirmed. However, data on deaths meeting the clinical case definition but pending laboratory confirmation may be entered in the reporting system and listed as "Not Classified."

Cases entered into the reporting system cannot be deleted. Therefore cases entered with laboratory results pending that are determined to not be influenza -related should be classified as "Not a Case." Cases initially classified as confirmed but that are later determined to not be influenza-related should also be reclassified as "Not a Case."

Legionellosis (Legionella pneumophila) (Legionnaires' Disease) (Revised 2005)

Clinical description

Legionellosis is associated with two clinically and epidemiologically distinct illnesses: Legionnaires' disease, which is characterized by fever, myalgia, cough, and clinical or radiographic pneumonia; and Pontiac fever, a milder illness without pneumonia.

Laboratory criteria for diagnosis:

Suspect:

- By seroconversion: fourfold or greater rise in antibody titer to specific species or serogroups of *Legionella* other than *L. pneumophila* serogroup 1 (e.g., *L. micdadei*, *L. pneumophila* serogroup 6).
- By seroconversion: fourfold or greater rise in antibody titer to multiple species of *Legionella* using pooled antigen and validated reagents.
- By the detection of specific *Legionella* antigen or staining of the organism in respiratory secretions, lung tissue, or pleural fluid by direct fluorescent antibody (DFA) staining, immunohistochemstry (IHC), or other similar method, using validated reagents.
- By detection of *Legionella* species by a validated nucleic acid assay.

Confirmed:

- By culture: isolation of any *Legionella* organism from respiratory secretions, lung tissue, pleural fluid, or other normally sterile fluid.
- By detection of *Legionella pneumophila* serogroup 1 antigen in urine using validated reagents.

^{*}Serologic testing for influenza is available in a limited number of laboratories, and should only be considered as evidence of recent infection if a four-fold rise in influenza (HI) antibody titer is demonstrated in paired sera. Single serum samples are not interpretable.

• By seroconversion: fourfold or greater rise in specific serum antibody titer to *Legionella pneumophila* serogroup 1 using validated reagents.

Case classification

Suspect: a clinically compatible case that meets at least one of the presumptive (suspect) laboratory criteria.

 Travel-associated: a case that has a history of spending at least one night away from home, either in the same country of residence or abroad, in the ten days before onset of illness.

Confirmed: a clinically compatible case that meets at least one of the confirmatory laboratory criteria

 Travel-associated: a case that has a history of spending at least one night away from home, either in the same country of residence or abroad, in the ten days before onset of illness.

Listeriosis - (Adopted 1999)

Clinical description

In adults, invasive disease caused by *Listeria monocytogenes* manifests most commonly as meningitis or bacteremia; infection during pregnancy may result in fetal loss through miscarriage or stillbirth, or neonatal meningitis or bacteremia. Other manifestations can also be observed.

Laboratory criteria for diagnosis

- Isolation of *L. monocytogenes* from a normally sterile site (e.g., blood or cerbrospinal fluid [CSF] or, less commonly, joint, pleural, or pericardial fluid)
- In the setting of miscarriage or stillbirth, isolation of *L. monocytogenes* from placental or fetal tissue

Case classification

Confirmed: A clinically compatible case that is laboratory-confirmed

Lyme Disease (Borrelia burgdorferi)(Revised 2008)

This surveillance case definition was developed for national reporting of Lyme disease; it is not intended to be used in clinical diagnosis.

Clinical presentation

A systemic, tick-borne disease with protean manifestations, including dermatologic, rheumatologic, neurologic, and cardiac abnormalities. The best clinical marker for the disease is erythema migrans (EM), the initial skin lesion that occurs in 60%-80% of patients.

For purposes of surveillance, EM is defined as a skin lesion that typically begins as a red macule or papule and expands over a period of days to weeks to form a large round lesion, often with partial central clearing. A single primary lesion must reach greater than or equal to 5 cm in size across its largest diameter. Secondary lesions also may occur. Annular erythematous lesions occurring within several hours of a tick bite represent hypersensitivity reactions and do not qualify as EM. For most patients, the expanding EM lesion is accompanied by other acute symptoms, particularly fatigue, fever, headache, mildly stiff neck, arthralgia, or myalgia. These symptoms are typically intermittent. The diagnosis of EM must be made by a physician. Laboratory confirmation is recommended for persons with no known exposure.

For purposes of surveillance, late manifestations include any of the following when an alternate explanation is not found:

Musculoskeletal system. Recurrent, brief attacks (weeks or months) of objective joint swelling in one or a few joints, sometimes followed by chronic arthritis in one or a few joints. Manifestations not considered as criteria for diagnosis include chronic progressive arthritis not preceded by brief attacks and chronic symmetrical polyarthritis. Additionally, arthralgia, myalgia, or fibromyalgia syndromes alone are not criteria for musculoskeletal involvement.

Nervous system. Any of the following, alone or in combination: lymphocytic meningitis; cranial neuritis, particularly facial palsy (may be bilateral); radiculoneuropathy; or, rarely, encephalomyelitis. Encephalomyelitis must be confirmed by demonstration of antibody production against *Borrelia burgdorferi* in the cerebrospinal fluid (CSF), evidenced by a higher titer of antibody in CSF than in serum. Headache, fatigue, paresthesia, or mildly stiff neck alone, are not criteria for neurologic involvement.

Cardiovascular system. Acute onset of high-grade (2nd-degree or 3rd-degree) atrioventricular conduction defects that resolve in days to weeks and are sometimes associated with myocarditis. Palpitations, bradycardia, bundle branch block, or myocarditis alone are not criteria for cardiovascular involvement.

Laboratory evidence

For the purposes of surveillance, the definition of a qualified laboratory assay is (1) a positive culture for *B. burgdorferi*, (2) two-tier testing interpreted using established criteria [1], or (3) single-tier IgG immunoblot seropositivity interpreted using established criteria [1-4].

Exposure

Exposure is defined as having been (less than or equal to 30 days before onset of EM) in wooded, brushy, or grassy areas (i.e., potential tick habitats) in a county in which Lyme disease is endemic. A history of tick bite is not required.

Disease endemic to county

A county in which Lyme disease is endemic is one in which at least two confirmed cases have been acquired in the county or in which established populations of a known tick vector are infected with *B. burgdorferi*.

Case classification

Confirmed: a) a case of EM with a known exposure (as defined above), or b) a case of EM with laboratory evidence of infection (as defined above) and without a known exposure or c) a case with at least one late manifestation that has laboratory evidence of infection.

Probable: any other case of physician-diagnosed Lyme disease that has laboratory evidence of infection (as defined above).

Suspected: a) a case of EM where there is no known exposure (as defined above) and no laboratory evidence of infection (as defined above), or b) a case with laboratory evidence of infection but no clinical information available (e.g. a laboratory report).

Lyme disease reports will not be considered cases if the medical provider specifically states this is not a case of Lyme disease, or the only symptom listed is "tick bite" or "insect bite."

Malaria (Revised 3/95)

Clinical description

Signs and symptoms are variable, but most patients experience fever. In addition to fever, common associated symptoms include headache, back pain, chills, sweats, myalgias, nausea, vomiting, diarrhea, and cough. Untreated *Plasmodium falciparum* infection may lead to coma, renal failure, pulmonary edema, and death. The diagnosis should be considered for any person who has these symptoms who has traveled to an area where malaria is endemic. Asymptomatic parasitemia may occur among persons who have been long-term residents of areas in which malaria is endemic.

Laboratory criteria for diagnosis

• Demonstration of malaria parasites in blood films

Case classification

Confirmed: An episode of microscopically-confirmed malaria parasitemia in any person (symptomatic or asymptomatic) diagnosed in the United States, regardless of whether the person experienced previous episodes of malaria while outside the country

Comment

A subsequent attack experienced by the same person but caused by a different *Plasmodium* species is counted as an additional case. A subsequent attack experienced by the same person and caused by the same species in the United States may indicate a relapsing infection or treatment failure caused by drug resistance. Blood smears from questionable cases should be referred to the National Malaria Repository, CDC, for confirmation of the diagnosis.

Cases are also classified according to the following World Health Organization categories:

• Autochthonous: Indigenous: malaria acquired by mosquito transmission in an area where malaria is a regular occurrence

- *Introduced*: malaria acquired by mosquito transmission from an imported case in an area where malaria is not a regular occurrence
- Imported: malaria acquired outside a specific area (e.g., the United States and its territories)
- *Induced*: malaria acquired through artificial means (e.g., blood transfusion, common syringes, or malariotherapy)
- *Relapsing*: renewed manifestation (of clinical symptoms and/or parasitemia) of malaria infection that is separated from previous manifestations of the same infection by an interval greater than any interval resulting from the normal periodicity of the paroxysms
- Cryptic: an isolated case of malaria not epidemiologically linked to additional cases

Measles (Rubeola) Revised 2007

Clinical case definition

An illness characterized by all the following:

- a generalized rash lasting greater than or equal to 3 days
- a temperature greater than or equal to 101.0°F (greater than or equal to 38.3°C)
- cough, coryza, or conjunctivitis

Laboratory criteria for diagnosis

- Positive serologic test for measles immunoglobulin M antibody, or
- Significant rise in measles antibody level by any standard serologic assay, or
- Isolation of measles virus from a clinical specimen

Case classification

Suspected: any febrile illness accompanied by rash

Probable: a case that meets the clinical case definition, has noncontributory or no serologic or virologic testing, and is not epidemiologically linked to a confirmed case

Confirmed: a case that is laboratory confirmed or that meets the clinical case definition and is epidemiologically linked to a confirmed case. A laboratory-confirmed case does not need to meet the clinical case definition.

Epidemiologic Classification of Internationally-Imported and U.S-Acquired

Internationally imported case: An internationally imported case is defined as a case in which measles results from exposure to measles virus outside the United States as evidenced by at least some of the exposure period (7–21 days before rash onset) occurring outside the United States and rash onset occurring within 21 days of entering the United States and there is no known exposure to measles in the U.S. during that time. All other cases are considered U.S.-acquired.

U.S.-acquired case: An U.S.-acquired case is defined as a case in which the patient had not been outside the United States during the 21 days before rash onset or was known to have been exposed to measles within the United States.

U.S.-acquired cases are subclassified into four mutually exclusive groups:

Import-linked case: Any case in a chain of transmission that is epidemiologically linked to an internationally imported case.

Imported-virus case: a case for which an epidemiologic link to an internationally imported case was not identified, but for which viral genetic evidence indicates an imported measles genotype, i.e., a genotype that is not occurring within the United States in a pattern indicative of endemic transmission. An endemic genotype is the genotype of any measles virus that occurs in an endemic chain of transmission (i.e., lasting ≥ 12 months). Any genotype that is found repeatedly in U.S.-acquired cases should be thoroughly investigated as a potential endemic genotype, especially if the cases are closely related in time or location.

Endemic case: a case for which epidemiological or virological evidence indicates an endemic chain of transmission. Endemic transmission is defined as a chain of measles virus transmission that is continuous for ≥ 12 months within the United States.

Unknown source case: a case for which an epidemiological or virological link to importation or to endemic transmission within the U.S. cannot be established after a thorough investigation. These cases must be carefully assessed epidemiologically to assure that they do not represent a sustained U.S.-acquired chain of transmission or an endemic chain of transmission within the U.S.

Note: Internationally imported, import-linked, and imported-virus cases are considered collectively to be import-associated cases.

States may also choose to classify cases as "out-of-state-imported" when imported from another state in the United States. For national reporting, however, cases will be classified as either internationally imported or U.S.-acquired.

Meningococcal Disease (Neisseria meningitidis) (Revised 2005)

Clinical description

Meningococcal disease manifests most commonly as meningitis and/or meningococcemia that may progress rapidly to purpura fulminans, shock, and death. However, other manifestations might be observed.

Case classification

Suspect:

- Clinical purpura fulminans in the absence of a positive blood culture
- A clinically compatible case with gram negative diplococci from a normally sterile site (e.g., blood or CSF)

Probable: A clinically compatible case that has either:

• Evidence of *N. meningitidis* DNA using a validated polymerase chain reaction (PCR), obtained from a normally sterile site (e.g., blood or CSF) *,

OR

• Evidence of *N. meningitidis* antigen by immunohistochemistry (IHC) on formalin-fixed tissue or latex agglutination of CSF **,***

Confirmed: A clinically compatible case **AND** isolation of *Neisseria meningitidis* from a normally sterile site (e.g., blood or cerebrospinal fluid {CSF} or, less commonly, synovial, pleural, or pericardial fluid) or skin scrapings of purpuric lesions.

Mumps (Revised 2008

Clinical case definition

An illness with acute onset of unilateral or bilateral tender, self-limited swelling of the parotid and or other salivary gland(s), lasting at least 2 days, and without other apparent cause.

Clinically Compatible Illness

Infection with mumps virus may present as aseptic meningitis, encephalitis, hearing loss, orchitis, oophoritis, parotitis or other salivary gland swelling, mastitis or pancreatitis.

Laboratory criteria

- Isolation of mumps virus from clinical specimen, or
- Detection of mumps nucleic acid (e.g., standard or real time RT-PCR assays), or
- Detection of mumps IgM antibody, or
- Demonstration of specific mumps antibody response in absence of recent vaccination, either a four-fold increase in IgG titer as measured by quantitative assays, or a seroconversion from negative to positive using a standard serologic assay of paired acute and convalescent serum specimens.

Case Classification

Suspected: A case with clinically compatible illness or that meets the clinical case definition without laboratory testing, or a case with laboratory tests suggestive of mumps without clinical information.

^{*} Mothershed EA, Sacchi CT, Whitney AM, Barnett GA, Ajello GW, Schmink S, Mayer LW, Phelan M, Taylor TH Jr, Bernhardt SA, Rosenstein NE, Popovic T. 2004. Use of real-time PCR to resolve slide agglutination discrepancies in serogroup identification of *Neisseria meningitidis*. *J Clin Microbiol* 42:320-328.

^{**} Guarner J. Greer PW. Whitney A. Shieh WJ. Fischer M. White EH. Carlone GM. Stephens DS. Popovic T. Zaki SR. Pathogenesis and diagnosis of human meningococcal disease using immunohistochemical and PCR assays; *American Journal of Clinical Pathology.* 122(5):754-64, 2004 Nov.

^{***} Positive antigen test results from urine or serum samples are unreliable for diagnosing meningococcal disease.

Probable: A case that meets the clinical case definition without laboratory confirmation and is epidemiologically linked to a clinically compatible case.

Confirmed: A case that: 1) meets the clinical case definition or has clinically compatible illness, and 2) is either laboratory confirmed or is epidemiologically linked to a confirmed case.

Case Classification for Import Status

Internationally imported case: An internationally imported case is defined as a case in which mumps results from exposure to mumps virus outside the United States as evidenced by at least some of the exposure period (12–25 days before onset of parotitis or other mumps-associated complications) occurring outside the United States and the onset of parotitis or other mumps-associated complications within 25 days of entering the United States and no known exposure to mumps in the U.S. during that time. All other cases are considered U.S.-acquired cases.

U.S.-acquired case: A U.S.-acquired case is defined as a case in which the patient had not been outside the United States during the 25 days before onset of parotitis or other mumps-associated complications or was known to have been exposed to mumps within the United States.

U.S.-acquired cases are sub-classified into four mutually exclusive groups:

Import-linked case: Any case in a chain of transmission that is epidemiologically linked to an internationally imported case.

Imported-virus case: A case for which an epidemiologic link to an internationally imported case was not identified but for which viral genetic evidence indicates an imported mumps genotype, i.e., a genotype that is not occurring within the United States in a pattern indicative of endemic transmission. An endemic genotype is the genotype of any mumps virus that occurs in an endemic chain of transmission (i.e., lasting ≥12 months). Any genotype that is found repeatedly in U.S.-acquired cases should be thoroughly investigated as a potential endemic genotype, especially if the cases are closely related in time or location.

Endemic case: A case for which epidemiological or virological evidence indicates an endemic chain of transmission. Endemic transmission is defined as a chain of mumps virus transmission continuous for >12 months within the United States.

Unknown source case: A case for which an epidemiological or virological link to importation or to endemic transmission within the U.S. cannot be established after a thorough investigation. These cases must be carefully assessed epidemiologically to assure that they do not represent a sustained U.S.-acquired chain of transmission or an endemic chain of transmission within the U.S.

Note: Internationally imported, import-linked, and imported-virus cases are considered collectively to be import-associated cases.

Comment

With previous contact with mumps virus either through vaccination (particularly with 2 doses) or natural infection, serum mumps IgM test results may be negative; IgG test results may be positive at initial blood draw and viral detection in RT-PCR or culture may have low yield. Therefore, mumps cases should not be ruled out by negative laboratory results. Serologic tests should be interpreted with caution, as false positive and false negative results are possible with IgM tests.

Currently, there is insufficient information to determine whether any mumps strains are endemic to the United States or to distinguish endemic from non-endemic strains. States may also choose to classify cases as "out-of-state-imported" when imported from another state in the United States. For national reporting, however, cases will be classified as either internationally imported or U.S.-acquired.

States may also choose to classify cases as "out-of-state-imported" when imported from another state in the United States. For national reporting, however, cases will be classified as either internationally imported or U.S-acquired.

Pertussis (Revised 11/97)

Clinical Case Definition

A cough illness lasting ≥ 2 weeks with one of the following: paroxysms of coughing, inspiratory "whoop," or post-tussive vomiting, without other apparent cause (as reported by a health professional)

Laboratory criteria for diagnosis

- Isolation of *Bordetella pertussis* from clinical specimen
- Positive polymerase chain reaction (PCR) for *B. pertussis*

Case classification

Probable: a case meets the clinical case definition, is not laboratory confirmed, and is not epidemiologically linked to a laboratory-confirmed case

Confirmed: a case that is culture positive and in which an acute cough illness of any duration is present; or a case that meets the clinical case definition and is confirmed by positive PCR; or a case that meets the clinical case definition and is epidemiologically linked directly to a case confirmed by either culture or PCR.

Comment

The clinical case definition above is appropriate for endemic or sporadic cases. In outbreak settings, a case may be defined as a cough illness lasting ≥ 2 weeks (as reported by a health professional). Because some studies have documented that direct fluorescent antibody testing of nasopharyngeal secretions has low sensitivity and variable specificity, it should not be relied on as a criterion for laboratory confirmation*,**. Serologic testing for pertussis is available in some areas but is not standardized and, therefore, should not be relied on as a criterion for laboratory confirmation for national reporting purpose. Both probable and confirmed cases should be reported to the NNDSS.

Plague (Revised 9/96)

Clinical description

Plague is transmitted to humans by fleas or by direct exposure to infected tissues or respiratory droplets; the disease is characterized by fever, chills, headache, malaise, prostration, and leukocytosis that manifests in one or more of the following principal clinical forms:

- Regional lymphadenitis (bubonic plague)
- Septicemia without an evident bubo (septicemic plague)
- Plague pneumonia, resulting from hematogenous spread in bubonic or septicemic cases (secondary pneumonic plague) or inhalation of infectious droplets (primary pneumonic plague)
- Pharyngitis and cervical lymphadenitis resulting from exposure to larger infectious droplets or ingestion of infected tissues (pharyngeal plague)

Laboratory criteria for diagnosis

Presumptive

- Elevated serum antibody titer(s) to *Yersinia pestis* F1 antigen (without documented fourfold or greater change) in a patient with no history of plague vaccination or
- Detection of F1 antigen in a clinical specimen by fluorescent assay

Confirmatory

- Isolation of Y. pestis from a clinical specimen or
- Fourfold or greater change in serum antibody titer to *Y. pestis* fraction 1 F1 antigen
- * Broome CV, Fraser DW, English WJ. Pertussis--diagnostic methods and surveillance. In: Manclark CR, Hill JC, eds. International Symposium on Pertussis. Bethesda, MD: US Department of Health, Education, and Welfare, Public Health Service, National Institutes of Health, 1979; DHEW publication no. (NIH)79-1830:19-22.
- ** Halperin SA, Bortolussi R, Wort AJ. Evaluation of culture, immunofluorescence, and serology for the diagnosis of pertussis. J Clin Microbiol 1989;27:752-7.

Case classification

Suspected: A clinically compatible case without presumptive or confirmatory laboratory results.

Probable: A clinically compatible case with presumptive laboratory results.

Confirmed: A clinically compatible case with confirmatory laboratory results.

Poliomyelitis, Paralytic

Clinical Case Definition

Acute onset of a flaccid paralysis of one or more limbs with decreased or absent tendon reflexes in the affected limbs, without other apparent cause, and without sensory or cognitive loss

Case classification

Probable: a case that meets the clinical case definition

Confirmed: a case that meets the clinical case definition and in which the patient has a neurologic deficit 60 days after onset of initial symptoms, has died, or has unknown follow-up status.

Comment

All suspected cases of paralytic poliomyelitis are reviewed by a panel of expert consultants before final classification occurs. Confirmed cases are then further classified on epidemiologic and laboratory criteria.* Only confirmed cases are included in Table I in the MMWR. Suspected cases are enumerated in a footnote to the MMWR table.

Psittacosis (Revised 9/96)

Clinical description

An illness characterized by fever, chills, headache, photophobia, cough, and myalgia.

Laboratory criteria for diagnosis

- Isolation of *Chlamydia psittaci* from respiratory secretions, or
- Fourfold or greater increase in antibody against C. psittaci by complement fixation or microimmuno-fluorescence (MIF) to a reciprocal titer of ≥ 32 between paired acute- and convalescent-phase serum specimens or
- Presence of immunoglobulin M antibody against *C. Psittaci* by MIF to a reciprocal titer of ≥ 16

^{*} Sutter RW, Brink EW, Cochi SL, et al. A new epidemiologic and laboratory classification system for paralytic poliomyelitis cases. Am J Public Health 1989;79:495-8.

Case classification

Probable: a clinically compatible case that is epidemiologically linked to a confirmed case or that has supportive serology (e.g. C. psittaci titer of ≥ 32 in one or more serum specimens obtained after onset of symptoms)

Confirmed: a clinically compatible case that is laboratory confirmed

Comment

The serologic findings by CF noted above may also occur as a result of infection with *Chlamydia pneumoniae* or *Chlamydia trachomatis*. The MIF appears to be more specific for infection with *C. psittaci*, but experience with and availability of this newer test is more limited.

Q Fever (Coxiella burnetii)Revised 2008

Acute Q Fever

Clinical presentation

Acute fever usually accompanied by rigors, myalgia, malaise, and a severe retrobulbar headache. Fatigue, night-sweats, dyspnea, confusion, nausea, diarrhea, abdominal pain, vomiting, non-productive cough, and chest pain have also been reported. Severe disease can include acute hepatitis, atypical pneumonia with abnormal radiograph, and meningoencephalitis. Pregnant women are at risk for fetal death and abortion. Clinical laboratory findings may include elevated liver enzyme levels, leukocytosis, and thrombocytopenia. Asymptomatic infections may also occur.

Note: Serologic profiles of pregnant women infected with acute Q fever during gestation may progress frequently and rapidly to those characteristic of chronic infection.

Clinical evidence

Acute fever and one or more of the following: rigors, severe retrobulbar headache, acute hepatitis, pneumonia, or elevated liver enzyme levels.

Laboratory evidence

Laboratory confirmed:

- Serological evidence of a fourfold change in immunoglobulin G (IgG)-specific antibody titer to *C. burnetii* phase II antigen by indirect immunofluorescence assay (IFA) between paired serum samples, (CDC suggests one taken during the first week of illness and a second 3-6 weeks later, antibody titers to phase I antigen may be elevated or rise as well), or
- Detection of *C. burnetii* DNA in a clinical specimen via amplification of a specific target by polymerase chain reaction (PCR) assay, **or**
- Demonstration of *C. burnetii* in a clinical specimen by immunohistochemical methods (IHC), **or**
- Isolation of *C. burnetii* from a clinical specimen by culture.

Laboratory supportive:

- Has a single supportive IFA IgG titer of ≥1:128 to phase II antigen (phase I titers may be elevated as well).
- Has serologic evidence of elevated IgG or IgM antibody reactive with *C. burnetii* antigen by enzyme-linked immunosorbent assay (ELISA), dot-ELISA, or latex agglutination.

Note: For acute testing, CDC uses in-house IFA IgG testing (cutoff of \geq 1:128), preferring simultaneous testing of paired specimens, and does not use IgM results for routine diagnostic testing.

Case Classification

Confirmed acute Q fever: A laboratory confirmed case that either meets clinical case criteria or is epidemiologically linked to a lab confirmed case.

Probable acute Q fever: A clinically compatible case of acute illness (meets clinical evidence criteria for acute Q fever illness) that has laboratory supportive results for past or present acute disease (antibody to Phase II antigen) but is not laboratory confirmed.

Chronic Q Fever

Clinical presentation

Infection that persists for more than 6 months. Potentially fatal endocarditis may evolve months to years after acute infection, particularly in persons with underlying valvular disease. Infections of aneurysms and vascular prostheses have been reported. Immunocompromised individuals are particularly susceptible. Rare cases of chronic hepatitis without endocarditis, osteomyelitis, osteoarthritis, and pneumonitis have been described.

Clinical evidence

Newly recognized, culture-negative endocarditis, particularly in a patient with previous valvulopathy or compromised immune system, suspected infection of a vascular aneurysm or vascular prosthesis, or chronic hepatitis, osteomyelitis, osteoarthritis, or pneumonitis in the absence of other known etiology.

Laboratory evidence

Laboratory confirmed:

- Serological evidence of IgG antibody to *C. burnetii* phase I antigen ≥ 1:800 by IFA (while phase II IgG titer will be elevated as well; phase I titer is higher than the phase II titer), **or**
- Detection of *C. burnetii* DNA in a clinical specimen via amplification of a specific target by PCR assay, **or**
- Demonstration of C. burnetii antigen in a clinical specimen by IHC, or
- Isolation of *C. burnetii* from a clinical specimen by culture.

Laboratory supportive:

• Has an antibody titer to C. burnetii phase I IgG antigen \geq 1:128 and \leq 1:800 by IFA.

Note: Samples from suspected chronic patients should be evaluated for IgG titers to both phase I and phase II antigens. Current commercially available ELISA tests (which test only for phase 2) are not quantitative, cannot be used to evaluate changes in antibody titer, and hence are not useful for serological confirmation. IgM tests are not strongly supported for use in serodiagnosis of acute disease, as the response may not be specific for the agent (resulting in false positives) and the IgM response may be persistent. Complement fixation (CF) tests and other older test methods are neither readily available nor commonly used.

Serologic test results must be interpreted with caution, because baseline antibodies acquired as a result of historical exposure to Q fever may exist, especially in rural and farming areas.

Case Classification

Confirmed chronic Q fever: A clinically compatible case of chronic illness (meets clinical evidence criteria for chronic Q fever) that is laboratory confirmed for chronic infection.

Probable chronic Q fever: A clinically compatible case of chronic illness (meets clinical evidence criteria for chronic Q fever) that has laboratory supportive results for past or present chronic infection (antibody to Phase I antigen).

Exposure:

Exposure is usually via aerosol, is broadly interpreted, and may be unknown (especially for chronic infection), but often includes the presence of goats, sheep, or other livestock, especially during periods of parturition. Direct contact with animals is not required, and variable incubation periods may be dose dependent.

Rabies, Animal

Laboratory criteria for diagnosis

- A positive direct fluorescent antibody test (preferably performed on central nervous system tissue)
- Isolation of rabies virus (in cell culture or in a laboratory animal)

Case classification

Confirmed: a case that is laboratory confirmed

Rabies, Human

Clinical description

Rabies is an acute encephalomyelitis that almost always progresses to coma or death within 10 days of the first symptom.

Laboratory criteria for diagnosis

• Detection by direct fluorescent antibody of viral antigens in a clinical specimen (preferably the brain or the nerves surrounding hair follicles in the nape of the neck), or

- Isolation (in cell culture or in a laboratory animal) of rabies virus from saliva, cerebrospinal fluid (CSF) or central nervous system tissue, or
- Identification of a rabies-neutralizing antibody titer ≥ 5 (complete neutralization) in the serum or CSF of an unvaccinated person.

Case classification

Confirmed: a clinically compatible case that is laboratory confirmed

Comment

Laboratory confirmation by all of the above methods is strongly recommended.

Rocky Mountain spotted fever (RMSF) (Rickettsia rickettsii) Revised 2008

Clinical presentation

Rocky Mountain spotted fever (RMSF) is an illness caused by *Rickettsia rickettsii*, a bacterial pathogen transmitted to humans through contact with ticks. *Dermacentor* species of ticks are most commonly associated with infection, including *Dermacentor variabilis* (the American dog tick), *Dermacentor andersoni* (the Rocky Mountain wood tick), and more recently *Rhiphicephalus sanguineus* (the brown dog tick). Disease onset averages one week following a tick bite. Age-specific illness is highest for children and older adults. Illness is characterized by acute onset of fever, and may be accompanied by headache, malaise, myalgia, nausea/vomiting, or neurologic signs; a macular or maculopapular rash appears 4-7 days following onset in many (~80%) patients, often present on the palms and soles. RMSF may be fatal in as many as 20% of untreated cases, and severe, fulminant disease can occur.

Acute illness is best detected by polymerase chain reaction (PCR) and immunohistochemical methods (IHC) in skin biopsy specimens, and occasionally by PCR in appropriate whole blood specimens taken during the first week of illness, prior to antibiotic treatment. Serology can also be employed for detection, however an antibody response may not be detectable in initial samples, and paired acute and convalescent samples are essential for confirmation.

Clinical evidence

Any reported fever and one or more of the following: rash, headache, myalgia, anemia, thrombocytopenia, or any hepatic transaminase elevation.

Laboratory evidence

For the purposes of surveillance,

Laboratory confirmed:

- Serological evidence of a fourfold change in immunoglobulin G (IgG)-specific antibody titer reactive with *Rickettsia rickettsii* antigen by indirect immunofluorescence assay (IFA) between paired serum specimens (one taken in the first week of illness and a second 2-4 weeks later), **or**
- Detection of *R. rickettsii* DNA in a clinical specimen via amplification of a specific target by PCR assay, **or**
- Demonstration of spotted fever group antigen in a biopsy or autopsy specimen by IHC,
 or
- Isolation of *R. rickettsii* from a clinical specimen in cell culture.

Laboratory supportive:

• Has serologic evidence of elevated IgG or IgM antibody reactive with *R. rickettsii* antigen by IFA, enzyme-linked immunosorbent assay (ELISA), dot-ELISA, or latex agglutination.

Note: Current commercially available ELISA tests are not quantitative, cannot be used to evaluate changes in antibody titer, and hence are not useful for serological confirmation. IgM tests are not strongly supported for use in serodiagnosis of acute disease, as the response may not be specific for the agent (resulting in false positives) and the IgM response may be persistent. Complement fixation (CF) tests and other older test methods are neither readily available nor commonly used. CDC uses in-house IFA IgG testing (cutoff of $\geq 1:64$), preferring simultaneous testing of paired specimens, and does not use IgM results for routine diagnostic testing.

Exposure

Exposure is defined as having been in potential tick habitats within the past 14 days before onset of symptoms. A history of a tick bite is not required.

Case Classification

Confirmed: A clinically compatible case (meets clinical evidence criteria) that is laboratory confirmed.

Probable: A clinically compatible case (meets clinical evidence criteria) that has supportive laboratory results.

Suspect: A case with laboratory evidence of past or present infection but no clinical information available (e.g. a laboratory report).

Rubella (German measles) Revised 2007

Clinical case definition

An illness that has all the following characteristics:

- Acute onset of generalized maculopapular rash
- Temperature greater than 99.0 F (greater than 37.2 C), if measured
- Arthralgia/arthritis, lymphadenopathy, or conjunctivitis

Laboratory criteria for diagnosis

- Isolation of rubella virus, or
- Significant rise between acute- and convalescent-phase titers in serum rubella immunoglobulin G antibody level by any standard serologic assay, or
- Positive serologic test for rubella immunoglobulin M (IgM) antibody

Case classification

Suspected: any generalized rash illness of acute onset

Probable: a case that meets the clinical case definition, has no or noncontributory serologic or virologic testing, and is not epidemiologically linked to a laboratory-confirmed case

Confirmed: a case that is laboratory confirmed or that meets the clinical case definition and is epidemiologically linked to a laboratory-confirmed case

Epidemiologic Classification of Internationally-Imported and U.S.-Acquired

Internationally imported case: An internationally imported case is defined as a case in which rubella results from exposure to rubella virus outside the United States as evidenced by at least some of the exposure period (12–23 days before rash onset) occurring outside the United States and the onset of rash within 23 days of entering the United States and no known exposure to rubella in the U.S. during that time. All other cases are considered U.S.-acquired cases.

U.S.-acquired case: A U.S.-acquired case is defined as a case in which the patient had not been outside the United States during the 23 days before rash onset or was known to have been exposed to rubella within the United States.

U.S.-acquired cases are subclassified into four mutually exclusive groups:

Import-linked case: Any case in a chain of transmission that is epidemiologically linked to an internationally imported case.

Imported-virus case: a case for which an epidemiologic link to an internationally imported case was not identified but for which viral genetic evidence indicates an imported rubella genotype, i.e., a genotype that is not occurring within the United States in a pattern indicative of endemic transmission. An endemic genotype is the genotype of any rubella virus that occurs in an endemic chain of transmission (i.e., lasting ≥ 12 months). Any genotype that is found repeatedly in U.S.-acquired cases should be thoroughly investigated as a potential endemic genotype, especially if the cases are closely related in time or location.

Endemic case: a case for which epidemiological or virological evidence indicates an endemic chain of transmission. Endemic transmission is defined as a chain of rubella virus transmission continuous for >12 months within the United States.

Unknown source case: a case for which an epidemiological or virological link to importation or to endemic transmission within the U.S. cannot be established after a thorough investigation. These cases must be carefully assessed epidemiologically to assure that they do not represent a sustained U.S.-acquired chain of transmission or an endemic chain of transmission within the U.S.

Note: Internationally imported, import-linked, and imported-virus cases are considered collectively to be import-associated cases.

States may also choose to classify cases as "out-of-state-imported" when imported from another state in the United States. For national reporting, however, cases will be classified as either internationally imported or U.S.-acquired.

Comments

Serum rubella IgM test results that are false positives have been reported in persons with other viral infections (e.g., acute infection with Epstein-Barr virus [infectious mononucleosis], recent cytomegalovirus infection, and parvovirus infection) or in the presence of rheumatoid factor. Patients who have laboratory evidence of recent measles infection are excluded.

Rubella, Congenital Syndrome (Revised 5/99)

Clinical description

Presence of any defect(s) or laboratory data consistent with congenital rubella infection. Infants with congenital rubella syndrome usually present with more than one sign or symptom consistent with congenital rubella infection. However, infants may present with a single defect. Deafness is most common single defect.

Laboratory criteria for diagnosis

- Isolation of rubella virus, or
- Demonstration of rubella-specific immunoglobulin M (IgM) antibody, or
- An infant's rubella antibody level that persists at a higher level and for a longer period of time than expected from passive transfer of maternal antibody (i.e., rubella titer that does not drop at the expected rate of a twofold dilution per month)
- PCR positive rubella virus

Clinical Case Definition

An illness usually manifesting in infancy resulting from rubella infection in utero and characterized by signs or symptoms from the following categories:

- Cataracts/congenital glaucoma, congenital heart disease, (most commonly patent ductus arteriosus, peripheral pulmonary artery stenosis), loss of hearing, pigmentary retinopathy.
- Purpura, hepatosplenomegaly, jaundice, microcephaly, mental retardation, meningoencephalitis, radiolucent bone disease.

Case classification

Suspected: a case with some compatible clinical findings but not meeting the criteria for a probable case.

Probable: a case that is not laboratory confirmed and that has any two complications listed in paragraph a) of the clinical case definition or one complication from paragraph a) and one from paragraph b), and lacks evidence of any other etiology.

Confirmed: a clinically consistent case that is laboratory confirmed.

Infection Only: a case that demostrates laboratory evidence of infection, but without any clinical symptoms or signs

Comment

In probable cases, either or both of the eye-related findings (cataracts and congenital glaucoma) count as a single complication. In cases classified as infection only, if any compatible signs or symptoms (e.g., hearing loss) are identified later, the case is reclassified as confirmed.

Salmonellosis (Salmonella spp.) Revised 2005

Clinical description

An illness of variable severity commonly manifested by diarrhea, abdominal pain, nausea, and sometimes vomiting. Asymptomatic infections may occur, and the organism may cause extraintestinal infections.

Laboratory criteria for diagnosis

Isolation of Salmonella from a clinical specimen.

Case classification

Probable: a clinically compatible case that is epidemiologically linked to a confirmed case.

Confirmed: a case that meets the laboratory criteria for diagnosis. When available, O and H antigen serotype characterization should be reported.

Comment

For users of the legacy National Notifiable Diseases Surveillance System, laboratory-confirmed isolates are also reported via the Public Health Laboratory Information System (PHLIS), which is managed by the Foodborne and Diarrheal Diseases Branch, Division of Bacterial and Mycotic Diseases, National Center for Infectious Diseases, CDC. The National Electronic Disease Surveillance System (NEDSS) or NEDSS compatible systems will eventually replace PHLIS and NETSS; users of NEDSS or compatible systems which report to CDC should not report via PHLIS. Both asymptomatic infections and infections at sites other than the gastrointestinal tract, if laboratory confirmed, are considered confirmed cases that should be reported.

Shigellosis (Shigella spp.) Revised 2005

Clinical description

An illness of variable severity characterized by diarrhea, fever, nausea, cramps, and tenesmus. Asymptomatic infections may occur.

Laboratory criteria for diagnosis

• Isolation of *Shigella* from a clinical specimen

Case classification

Probable: a clinically compatible case that is epidemiologically linked to a confirmed case.

Confirmed: a case that meets the laboratory criteria for diagnosis. When available, O antigen serotype characterization should be reported.

Comment

For users of the legacy National Electronic Telecommunications System for Surveillance (NETSS), laboratory-confirmed isolates are also reported via the Public Health Laboratory Information System (PHLIS), which is managed by the Foodborne and Diarrheal Diseases Branch, Division of Bacterial and Mycotic Diseases, National Center for Infectious Diseases, CDC. The National Electronic Disease Surveillance System (NEDSS) or NEDSS compatible systems will eventually replace PHLIS; users of NEDSS or compatible systems which report to CDC should not report via PHLIS.

Both asymptomatic infections and infections at sites other than the gastrointestinal tract, if laboratory confirmed, are considered confirmed cases that should be reported.

Smallpox (Variola) Revised 2004

Clinical Case Definition

An illness with acute onset of fever $\ge 101^\circ$ F ($\ge 38.3^\circ$ C) followed by a rash characterized by firm, deep seated vesicles or pustules in the same stage of development without other apparent cause. Clinically consistent cases are those presentations of smallpox that do not meet this classical clinical case definition: a) hemorrhagic type, b) flat type, and c) *variola sine eruptione*. (Detailed clinical description is available on the CDC web site, see URL: http://www.bt.cdc.gov/agent/smallpox/index.asp).

Laboratory Criteria

Polymerase chain reaction (PCR) identification of variola DNA in a clinical specimen, **OR**

Isolation of smallpox (variola) virus from a clinical specimen (Level D laboratory only; confirmed by variola PCR).

Note: Indications for laboratory testing of patients with suspected smallpox should be followed as described in detail in Guide A of the CDC Smallpox Response Plan. Laboratory diagnostic testing for variola virus should be conducted in Level C or D laboratories only.

Case Classification

Confirmed: case of smallpox that is laboratory confirmed, or a case that meets the clinical case definition that is epidemiologically linked to a laboratory confirmed case.

Probable: A case that meets the clinical case definition, or a clinically consistent case that does not meet the clinical case definition and has an epidemiological link to a confirmed case of smallpox.

Suspected: A case with a generalized, acute vesicular or pustular rash illness with fever preceding development of rash by 1-4 days.

Exclusion Criteria: A case may be excluded as a suspect or probable smallpox case if an alternative diagnosis fully explains the illness or appropriate clinical specimens are negative for laboratory criteria for smallpox.

Note: The smallpox case definition is to be used only during post-event surveillance. The case definition described in Guide A of the Smallpox Response Plan and Guidelines (Version 3) on the CDC bioterrorism preparedness website (URL:

http://www.bt.cdc.gov/agent/smallpox/response-plan/index.asp) includes different criteria for a

suspected case than the smallpox case definition the Council of State and Territorial Epidemiologists approved for use in the National Notifiable Diseases Surveillance System (NNDSS). The smallpox case definition on the CDC bioterrorism web site is more sensitive and less specific than the case definition for the NNDSS, in that a "suspect" case is defined as: "a case with febrile rash illness with fever preceding the development of rash by 1-4 days."

Vancomycin-intermediate *Staphylococcus aureus* (VISA), and Vancomycin-resistant *Staphylococcus aureus* (VRSA) 2007

Clinical Description

S. aureus can produce a variety of syndromes with clinical manifestations including skin and soft tissue infections, empyema, bloodstream infection, pneumonia, osteomyelitis, septic arthritis, endocarditis, sepsis, and meningitis. *S. aureus* may also colonize individuals who remain asymptomatic. The most frequent site of S. aureus colonization is the nares.

Laboratory Criteria

- Isolation of S. aureus from any body site. **AND**
- Intermediate or resistance of the *S. aureus* isolate to vancomycin, detected and defined according to Clinical and Laboratory Standards Institute (CLSI, formerly NCCLS) approved standards and recommendations (Minimum Inhibitory Concentration [MIC]=4-8 μg/ml for VISA and MIC≥16 μg/ml for VRSA).

Case Classification

Confirmed: A case of vancomycin-intermediate or vancomycin-resistant *S. aureus* that is laboratory-confirmed (MIC=4-8 μg/ml for VISA and MIC≥16 μg/ml for VRSA).

Reference

Clinical and Laboratory Standards Institute/NCCLS. Performance Standards for Antimicrobial Susceptibility Testing. Sixteenth informational supplement. M100-S16. Wayne, PA: CLSI, 2006.

Streptococcus pneumoniae, Drug-Resistant Invasive Disease (DRSP) Revised 2007

Clinical description

Streptococcus pneumoniae causes many clinical syndromes, depending on the site of infection (e.g., acute otitis media, pneumonia, bacteremia, or meningitis).

Laboratory criteria for diagnosis

- Isolation of *S. pneumoniae* from a normally sterile site (e.g., blood, cerebrospinal fluid, or, less commonly, joint, pleural, or pericardial fluid) and
- "Nonsusceptible" isolate (i.e., intermediate- or high-level resistance of the *S. pneumoniae* isolate to at least one antimicrobial agent currently approved for use in treating pneumococcal infection. *,**

^{*} National Committee for Clinical Laboratory Standards. Performance standards for antimicrobial susceptibility testing. Villanova, PA: National Committee for Clinical Laboratory Standards, 1994;14(16); NCCLS document M100-S5.

^{**} CDC. Defining the public health impact of drug-resistant Streptococcus pneumoniae: report of a working group. MMWR 1996;45(No. RR-1).

Resistance defined by National Committee for Clinical Laboratory Standards (NCCLS)-approved methods and NCCLS-approved interpretive minimum inhibitory concentration (MIC) standards ($\mu g/mL$) for *S. pneumoniae*. NCCLS recommends that all invasive *S. pneumoniae* isolates found to be "possibly resistant" to beta-lactams (i.e., an oxacillin zone size of less than 20 mm) by oxacillin screening should undergo further susceptibility testing by using a quantitative MIC method acceptable for penicillin, extended-spectrum cephalosporins, and other drugs as clinically indicated .*

Case classification

Probable: a clinically compatible case caused by laboratory-confirmed culture of *S. pneumoniae* identified as "nonsusceptible" (i.e., an oxacillin zone size of less than 20 mm) when oxacillin screening is the only method of antimicrobial susceptibility testing performed

Confirmed: a clinically compatible case that is laboratory confirmed

Comment

The difference between this case definition and the previous case definition for this condition is the inclusion of new case classifications for reporting purposes.

Case classifications for Drug Resistant Streptococcus pneumoniae (DRSP) and Invasive Pneumococcal Disease (IPD) are modified as listed below:

- Isolates causing IPD from children less than five years of age for which antibacterial susceptibilities are available and determined to be DRSP should be reported only as DRSP (event code 11720).
- Isolates causing IPD from children less than five years of age which are susceptible, or for which susceptibilities are not available should be reported ONLY as IPD in children less than five years of age (event code 11717).

Streptococcus pneumoniae, Invasive Disease Non-Drug Resistant, in Children Less Than 5 Years of Age (Invasive Pneumococcal Disease) Revised 2007

Clinical description

Streptococcus pneumoniae causes many clinical syndromes, depending on the site of infection (e.g., acute otitis media, pneumonia, bacteremia, or meningitis). Starting in 2000, a conjugate pneumococcal vaccine is recommended for prevention of pneumococcal disease in the pediatric population.

Laboratory criteria for diagnosis

Isolation of *S. pneumoniae* from a normally sterile site (e.g., blood, cerebrospinal fluid, or, less commonly, joint, pleural, or pericardial fluid)

^{*} National Committee for Clinical Laboratory Standards. Performance standards for antimicrobial susceptibility testing. Villanova, PA: National Committee for Clinical Laboratory Standards, 1994;14(16); NCCLS document M100-S5.

Case classification

Confirmed: a clinically compatible case in a child less than five years of age caused by laboratory-confirmed culture of *S. pneumoniae* from a normally sterile site

Comment

The difference between this case definition and the previous case definition for this condition is the inclusion of new case classifications for reporting purposes.

Case classifications for Drug Resistant Streptococcus pneumoniae (DRSP) and Invasive Pneumococcal Disease (IPD) are modified as listed below:

- Isolates causing IPD from children less than five years of age for which antibacterial susceptibilities are available and determined to be DRSP should be reported only as DRSP (event code 11720).
- Isolates causing IPD from children less than five years of age which are susceptible, or for which susceptibilities are not available should be reported ONLY as IPD in children less than five years of age (event code 11717).

Syphilis (All Definitions Revised 9/96)

Syphilis is a complex sexually transmitted disease that has a highly variable clinical course. Classification by a clinician with expertise in syphilis may take precedence over the following case definitions developed for surveillance purposes.

Syphilis, primary

Clinical description

A stage of infection with *Treponema pallidum* characterized by one or more chancres (ulcers); chancres may vary considerably in clinical appearance.

Laboratory criteria for diagnosis

• Demonstration of *T. pallidum* in clinical specimens by darkfield microscopy, fluorescent antibody (DFA-TP), or equivalent methods

Case classification

Probable: a clinically compatible case with one or more ulcers (chancres) consistent with primary syphilis and a reactive serologic test (non-treponemal: Venereal Disease Research Laboratory [VDRL] or Rapid Plasma Reagin [RPR]); treponemal: fluorescent treponemal antibody-absorbed [FTA-ABS] or microhem-agglutination assay for antibody to *T. pallidum* [MHA-TP])

Confirmed: a clinically compatible case that is laboratory confirmed

Syphilis, secondary

Clinical description

A stage of infection caused by T. pallidum and characterized by localized or diffuse mucocutaneous lesions, often with generalized lymphadenopathy. The primary chancre may still be present.

Laboratory criteria for diagnosis

• Demonstration of T. pallidum in clinical specimens by darkfield microscopy, DFA-TP, or equivalent methods

Case classification

Probable: a clinically compatible case with a nontreponemal (VDRL or RPR) titer ≥ 4 .

Confirmed: a clinically compatible case that is laboratory confirmed

Syphilis, latent

Clinical description

A stage of infection caused by *T. pallidum* in which organisms persist in the body of the infected person without causing symptoms or signs. Latent syphilis is subdivided into early, late, and unknown categories based upon the duration of infection.

Case classification

Probable: no clinical signs or symptoms of syphilis and the presence of one of the following:

- No past diagnosis of syphilis, a reactive nontreponemal test (i.e., VDRL or RPR), and a reactive treponemal test (i.e., FTA-ABS or MHA-TP)
- A past history of syphilis therapy and a current nontreponemal test titer demonstrating fourfold or greater increase from the last nontreponemal test titer

Syphilis, early latent

Clinical description

A subcategory of latent syphilis. When initial infection has occurred within the previous 12 months, latent syphilis is classified as early latent.

Case classification

Probable: latent syphilis (see Syphilis, latent) in a person who has evidence of having acquired the infection within the previous 12 months based on one or more of the following criteria:

- Documented seroconversion or fourfold or greater increase in titer of a nontreponemal test in the past 12 months
- A history of symptoms consistent with primary or secondary syphilis in the past 12 months
- A history of sexual exposure to a partner who had confirmed or probable primary or secondary syphilis, or probable early latent syphilis, (documented independently as duration <1 year)
- Reactive nontreponemal and treponemal tests from a person whose only possible exposure occurred within the preceding 12 months

Syphilis, late latent

Clinical description

A subcategory of latent syphilis. When initial infection has occurred >1 year previously, latent syphilis is classified as late latent.

Case classification

Probable: latent syphilis (see Syphilis, latent) of a patient who shows no evidence of having acquired the disease within the past 12 months (see Syphilis, early latent) and whose age and titer do not meet the criteria specified for latent syphilis of unknown duration.

Syphilis, latent, of unknown duration

Clinical description

A subcategory of latent syphilis. When the date of initial infection cannot be established as occurring within the previous year, and the patient's age and titer meet criteria described below, latent syphilis is classified as latent syphilis of unknown duration.

Case classification

Probable: latent syphilis (see Syphilis, latent) that does not meet the criteria for early latent syphilis, and the patient is 13-35 years of age with a nontreponemal titer ≥ 32 .

Neurosyphilis

Clinical description

Evidence of central nervous system infection with *T. pallidum*

Laboratory criteria for diagnosis

• A reactive serologic test for syphilis and reactive VDRL in cerebrospinal fluid (CSF)

Case classification

Probable: syphilis of any stage, a negative VDRL in CSF, and both of the following:

- Elevated CSF protein or leukocyte count in the absence of other known causes of these abnormalities
- Clinical symptoms or signs consistent with neurosyphilis without other known causes for these clinical abnormalities

Confirmed: syphilis, of any stage, that meets the laboratory criteria for neurosyphilis

Syphilis, late with clinical manifestations other than neurosyphilis (late benign syphilis and cardiovascular syphilis).

Clinical description

Clinical manifestations of late syphilis other than neurosyphilis may include inflammatory lesions of the cardiovascular system, skin, and bone. Rarely, other structures (e.g. the upper and lower respiratory tracts, mouth, eye, abdominal organs, reproductive organs, lymph nodes, and skeletal muscle) may be involved. Late syphilis usually becomes clinically manifest only after a period of 15 to 30 years of untreated infection.

Laboratory criteria for diagnosis

Demonstration of *T. pallidum* in late lesions by fluorescent antibody or special stains (although organisms are rarely visualized in late lesions).

Case classification

Probable: characteristic abnormalities or lesions of the cardiovascular system, skin, bone or other structures with a reactive treponemal test, in the absence of other known causes of these

abnormalities, and without CSF abnormalities and clinical symptoms or signs consistent with neurosyphilis.

Confirmed: A clinically compatible case that is laboratory confirmed.

Comment:

Analysis of CSF for evidence of neurosyphilis is necessary in the evaluation of late syphilis with clinical manifestations.

Syphilitic Stillbirth

Clinical description

A fetal death that occurs after a 20 week gestation or in which the fetus weighs >500 g, and the mother had untreated or inadequately treated* syphilis at delivery.

* Inadequate treatment consists of any nonpenicillin therapy or penicillin administered <30 days before delivery.

Comment

For reporting purposes, syphilitic stillbirths should be reported as cases of congenital syphilis.

Syphilis, Congenital (Revised 9/96)

Clinical description

A condition caused by infection *in utero* with *Treponema pallidum*. A wide spectrum of severity exists, and only severe cases are clinically apparent at birth. An infant (<2 years) may have signs such as hepatosplenomegaly, rash, condyloma lata, snuffles, jaundice (non-viral hepatitis), pseudoparalysis, anemia, or edema (nephrotic syndrome and/or malnutrition). An older child may have stigmata (e.g., interstitial keratitis, nerve deafness, anterior bowing of shins, frontal bossing, mulberry molars, Hutchinson teeth, saddle nose, rhagades, or Clutton joints).

Laboratory criteria for diagnosis

• Demonstration of *T. pallidum* by darkfield microscopy, fluorescent antibody, or other specific stains in specimens from lesions, placenta, umbilical cord, or autopsy material

Case classification

Probable: a condition affecting an infant whose mother had untreated or inadequately treated syphilis at delivery, regardless of signs in the infant; or an infant or child who has a reactive treponemal test for syphilis and any one of the following:

- Any evidence of congenital syphilis on physical examination
- Any evidence of congenital syphilis on radiographs of long bone
- A reactive cerebrospinal fluid (CSF) venereal disease research laboratory (VDRL)
- An elevated CSF cell count or protein (without other cause)
- A reactive fluorescent treponemal antibody absorbed--19S-IgM antibody test or IgM enzyme linked immunosorbent assay

Confirmed: a case that is laboratory confirmed

Comment

Congenital and acquired syphilis may be difficult to distinguish when a child is seropositive after infancy. Signs of congenital syphilis may not be obvious, and stigmata may not yet have developed. Abnormal values for CSF VDRL, cell count, and protein, as well as IgM antibodies, may be found in either congenital or acquired syphilis. Findings on radiographs of long bones may help because radiographic changes in the metaphysis and epiphysis are considered classic signs of congenitally acquired syphilis. The decision may ultimately be based on maternal history and clinical judgment. In a young child, the possibility of sexual abuse should be considered as a cause of acquired rather than congenital syphilis, depending on the clinical picture. For reporting purposes, congenital syphilis includes cases of congenitally acquired syphilis among infants and children as well as syphilitic stillbirths.

Tetanus (Revised 9/96)

Clinical Case Definition

Acute onset of hypertonia and/or painful muscular contractions (usually of the muscles of the jaw and neck) and generalized muscle spasms without other apparent medical cause

Case classification

Confirmed: a clinically compatible case, as reported by a health-care professional

Trichinosis (Revised 9/96)

Clinical description

A disease caused by ingestion of *Trichinella* larvae. The disease has variable clinical manifestations. Common signs and symptoms among symptomatic persons include eosinophilia, fever, myalgia, and periorbital edema.

Laboratory criteria for diagnosis

- Demonstration of *Trichinella* larvae in tissue obtained by muscle biopsy, or
- Positive serologic test for *Trichinella*.

Case classification

Confirmed: a clinically compatible case that is laboratory confirmed

Comment

In an outbreak setting, at least one case must be laboratory confirmed. Associated cases should be reported as confirmed if the patient shared an epidemiologically implicated meal or ate an epidemiologically implicated meat product and has either a positive serology for trichinosis or a clinically compatible case.

Tuberculosis (Revised 9/96)

Clinical description

A chronic bacterial infection due to *Mycobacterium tuberculosis*, characterized pathologically by the formation of granulomas. The most common site of infection is the lung, but other organs may be involved.

Clinical Case Definition

A case that meets the following criteria:

- A positive tuberculin skin test
- Other signs and symptoms compatible with tuberculosis, (e.g., an abnormal, unstable [i.e., worsening or improving] chest radiograph, or clinical evidence of current disease)
- Treatment with two or more antituberculosis medications
- Completed diagnostic evaluation

Laboratory criteria for diagnosis

- Isolation of *M. tuberculosis* from a clinical specimen* or
- Demonstration of *M. tuberculosis* from a clinical specimen by nucleic acid amplification test** or
- Demonstration of acid-fast bacilli in clinical specimen when a culture has not been or cannot be obtained

Case classification

Confirmed: a case that meets the clinical case definition or is laboratory confirmed.

Comment

A case should not be counted twice within any consecutive 12 month period. However, cases in which the patients had previously had verified disease should be reported again if the patients were discharged from treatment. Cases also should be reported again if patients were lost to supervision >12 months and disease can be verified again. Mycobacterial diseases other than those caused by *M. tuberculosis* complex should not be counted in tuberculosis morbidity statistics unless there is concurrent tuberculosis.

Tularemia (Adopted 1999)

Clinical description

An illness characterized by several distinct forms, including the following:

- Ulceroglandular: cutaneous ulcer with regional lymphadenopathy Glandular: regional lymphadenopathy with no ulcer
- Oculoglandular: conjunctivitis with preauricular lymphadenopathy
- Oropharyngeal: stomatitis or pharyngitis or tonsillitis and cervical lymphadenopathy
- Intestinal: intestinal pain, vomiting, and diarrhea
- Pneumonic: primary pleuropulmonary disease
- Typhoidal: febrile illness without early localizing signs and symptoms

Clinical diagnosis is supported by evidence or history of a tick or deerfly bite, exposure to tissue of a mammalian host of *Francisella tularensis*, or exposure to potentially contaminated water.

*Use of rapid identification techniques for M. tuberculosis (e.g., DNA probes and mycolic acids high-pressure liquid chromatography performed on a culture from a clinical specimen) are acceptable under this criterion. **Nucleic acid amplification (NAA) tests must be accompanied by culture for mycobacteria species. However, for surveillance purposes, CDC will accept results obtained from NAA tests approved by the Food and Drug Administration (FDA) and used according to the approved product labeling on the package insert. Current FDA-approved NAA tests are only approved for smear-positive respiratory specimens.

Laboratory criteria for diagnosis

Presumptive

- Elevated serum antibody titer(s) to *F. tularensis* antigen (without documented fourfold or greater change) in a patient with no history of tularemia vaccination or
- Detection of F. tularensis in a clinical specimen by fluorescent assay

Confirmatory

- Isolation of F. tularensis in a clinical specimen or
- Fourfold or greater change in serum antibody titer to F. tularensis antigen

Case classification

Probable: a clinically compatible case with laboratory results indicative of presumptive infection *Confirmed*: a clinically compatible case with confirmatory laboratory results

Typhoid Fever

Clinical description

An illness caused by *Salmonella typhi* that is often characterized by insidious onset of sustained fever, headache, malaise, anorexia, relative bradycardia, constipation or diarrhea, and nonproductive cough. However, many mild and atypical infections occur. Carriage of *S. typhi* may be prolonged.

Laboratory criteria for diagnosis

Isolation of S. typhi from blood, stool, or other clinical specimen

Case classification

Probable: a clinically compatible case that is epidemiologically linked to a confirmed case in an outbreak

Confirmed: a clinically compatible case that is laboratory confirmed

Comment

Isolation of the organism is required for confirmation. Serologic evidence alone is not sufficient for diagnosis. Asymptomatic carriage should not be reported as typhoid fever.

Isolates of *S. typhi* are reported to the Foodborne and Diarrheal Diseases Branch, National Center for Infectious Diseases, CDC, through the Public Health Laboratory Information System. (See *Salmonella*.)

Varicella (Chickenpox) Revised 1999

Clinical case definition

An illness with acute onset of diffuse (generalized) maculo-papulovesicular rash without other apparent cause.

Laboratory criteria for diagnosis

• Isolation of varicella virus from a clinical specimen, or

- Direct fluorescent antibody (DFA), or
- Polymerase chain reaction (PCR), or
- Significant rise in serum varicella immunoglobulin G (IgG) antibody level by any standard serologic assay

Case classification

Probable: a case that meets the clinical case definition, is not laboratory confirmed, and is not epidemiologically linked to another probable or confirmed case

Confirmed: a case that is laboratory confirmed or that meets the clinical case definition and is epidemiologically linked to a confirmed or probable case

Notes

Two probable cases that are epidemiologically linked would be considered confirmed, even in the absence of laboratory confirmation.

In vaccinated persons who develop varicella more than 42 days after vaccination (breakthrough disease), the disease is almost always mild with fewer than 50 skin lesions and shorter duration of illness. The rash may also be atypical in appearance (maculopapular with few or no vesicles). Laboratory confirmation of cases of varicella is not routinely recommended; laboratory confirmation is recommended for fatal cases and in other special circumstances.

Vibriosis (Non-cholera *Vibrio spp.*) Revised 2007

Clinical description

An infection of variable severity characterized by diarrhea and vomiting, primary septicemia, or wound infections. Asymptomatic infections may occur, and the organism may cause extraintestinal infections.

Laboratory criteria for diagnosis

Isolation of *Vibrio spp.* other than toxigenic *Vibrio cholerae* O1 or O139 from a clinical specimen. Infections due to toxigenic *Vibrio cholerae* O1 or O139 are reportable as cholera.

Case classification

Confirmed: A case that meets the laboratory criteria for diagnosis. Note that species identification and, if applicable, serotype designation (i.e., *Vibrio cholerae* non-O1/non-O139) should be reported.

Probable: A clinically-compatible symptomatic case that is epidemiologically linked to a confirmed case.

Comment

In addition to reporting through the National Notifiable Diseases Surveillance System (NNDSS), CDC requests that states collect information on the standard surveillance form for Cholera and Other Vibrio Illness Surveillance System (COVISS), available at: http://www.cdc.gov/foodborneoutbreaks/documents/cholera vibrio report.pdf. CDC intends to integrate the COVISS form into the National Electronic Diseases Surveillance System (NEDSS) in the future. Reporting sites should use the COVISS reporting form until the integration is complete and COVISS data can be transmitted to CDC. CDC requests that Vibrio cholerae and Vibrio parahaemolyticus isolates be referred to the Foodborne and Diarrheal Diseases Laboratory for characterization.

Yellow Fever

Clinical description

A mosquito-borne, viral illness characterized by acute onset and constitutional symptoms followed by a brief remission and a recurrence of fever, hepatitis, albuminuria, and symptoms and, in some cases, renal failure, shock, and generalized hemorrhages

Laboratory criteria for diagnosis

- Fourfold or greater rise in yellow fever antibody titer in a patient who has no history of recent yellow fever vaccination, and cross-reactions to other flaviviruses have been excluded or
- Demonstration of yellow fever virus, antigen, or genome in tissue, blood, or other body fluid

Case classification

Probable: a clinically compatible case with supportive serology (stable elevated antibody titer to yellow fever virus, [e.g., \geq 32 by complement fixation, \geq 256 by immunofluorescence assay, \geq 320 by hemagglutination inhibition, \geq 160 by neutralization, or a positive serologic result by immunoglobulin M-capture enzyme immunoassay]. Cross-reactive serologic reactions to other flaviviruses must be excluded, and the patient must not have a history of yellow fever vaccination.)

Confirmed: a clinically compatible case that is laboratory confirmed

Case Definitions

The following case definitions and data elements are recommended for use by all surveillance systems gathering information on traumatic brain and spinal cord injuries. This standardization will allow us to collect data that can be compared across time and between jurisdictions. As a result, we will be better able to target efforts to prevent these injuries and their consequences.

For the purposes of public health surveillance, jurisdictions may elect to ascertain cases of traumatic brain injury either from clinical records or from existing uniform data systems. Case definitions are presented for both types of ascertainment.

Traumatic Brain Injury

Clinical case definition

For surveillance systems using data from clinical records, a case of traumatic brain injury (craniocerebral trauma) is defined either

- As an occurrence of injury to the head that is documented in a medical record, with one or more of the following conditions attributed to head injury*:
- 1. Observed or self-reported decreased level of consciousness**
- 2. Amnesia*
- 3. Skull Fracture
- 4. Objective neurological or neuropsychological abnormality****
- 5. Diagnosed intracranial lesion*
- As an occurrence of death resulting from trauma, with head injury listed on the death certificate, autopsy report, or medical examiner(s report in the sequence of conditions that resulted in death.

The clinical definition of traumatic brain injury excludes the following:

- Lacerations or contusions of the face, eye, ear, or scalp, without the other criteria listed above
- Fractures of facial bones, without other criteria listed above
- Birth trauma
- Primary anoxic, inflammatory, infectious, toxic, or metabolic encephalopathies that are not complications of head trauma
- Cancer
- Brain infarction (ischemic stroke) and intracranial hemorrhage (hemorrhagic stroke) without associated trauma

^{*}Injuries to the head may arise from blunt or penetrating trauma or from acceleration-deceleration forces.

^{**} Decreased level of consciousness refers to partial or complete loss of consciousness. This includes states described as obtundation, stupor, or coma.

^{***} Amnesia may include loss of memory for events immediately preceding the injury (retrograde amnesia), for the injury event itself, and for events subsequent to the injury (posttraumatic amnesia).

^{****} Neurological abnormalities are determined from neurological examination. Examples include abnormalities of speech (aphasia or dysphasia); or seizures acutely following head trauma. Neuropsychological abnormalities are determined from mental status and neuropsychological examinations. Examples include disorders of mental status (such as disorientation, agitation, or confusion) and other changes in cognition, behavior, or personality.

Examples of diagnosed intracranial lesions include traumatic intracranial hematomas or hemorrhage (epidural, subural, subarachnoid, or intracerebral), cerebral contusions or laceratins, or penetrating cerebral injuries (e.g., gunshot wounds). The diagnosis of such intracranial lesions is usually confirmed with a computed tompgraphy (CT) or magnetic resonance imaging (MRI) brain scan or by other neurodiagnostic procedures.

Uniform data systems case definition

For surveillance systems receiving case reports from coded death certificates or hospital discharge data, the following International Classification of Diseases, Ninth Revision (ICD-9) or International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM) diagnostic codes are included in the definition of traumatic brain injury:

Diagnostic Codes for Traumatic Brain Injuries					
800.B0801.9	Fracture of the vault or base of the skull				
803.B0804.9	Other and unqualified and multiple fractures of the skull				
	Intracranial injury, including concussion, contusion,				
850.B0854.1	laceration, and hemorrhage				

Additional cases of traumatic brain injury may be ascertained from death certificates coded as follows:

Diagnostic Codes for Traumatic Brain Injuries					
873.0B873.9	Other open wound of head*				

This code range should not be applied to intracranial injuries. However, reviews of data from death certificates
indicate that a substantial number of cases of intracranial injury, especially gunshot wounds, are mistakenly
given these codes. Suspected cases of head trauma that have been so coded may be confirmed by reviewing
medical records or death certificates.

Spinal Cord Injury

Clinical case definition

For surveillance systems using data from clinical records, a case of spinal cord injury is defined as the occurrence of an acute traumatic lesion of neural elements in the spinal canal (spinal cord and cauda equina), resulting in temporary or permanent sensory deficit, motor deficit, or bowel or bladder dysfunction.

The clinical definition of spinal cord injury *excludes* the following:

- Intervertebral disc disease (ICD-9-CM 722)
- Vertebral injuries in the absence of spinal cord injury

Nerve root avulsions and injuries to nerve roots and peripheral nerves outside the spinal canal

- Birth trauma
- Cancer, spinal cord vascular disease, and other nontraumatic spinal cord diseases

Uniform data systems case definition

For surveillance systems receiving case reports from coded death certificates or hospital discharge data, the following ICD-9 or ICD-9-CM* diagnostic codes should be used to define acute spinal cord injury:

Diagnostic Codes for Spinal Cord Injuries					
806.0B806.9	Fracture of vertebral column with spinal cord lesion				
952.0B952.9	Spinal cord lesion without evidence of spinal bone injury				

Additional cases of spinal cord injury may be ascertained from hospital discharge data and death certificates codes as follows:

Diagnostic Codes for Traumatic Brain Injuries				
	Fracture of vertebral column without mention of spinal cord			
805.0B805.9	lesion			
907.2	Late effect of spinal cord injury			
953.0B953.9	Injury to nerve roots and spinal plexus			

However, since these categories are less specific than those listed above, individual medical or other records should be reviewed to confirm potential cases.

^{*} Note: ICD-9 codes are used for coding death certificates. ICD-9-CM codes are used for morbidity data. The codes are comparable except that ICD-9-CM codes include a fifth digit not found in ICD-9 codes.

Appendix D

Control of Rabies in Animals

Reprinted from Centers for Disease Control and Prevention Compendium of Animal Rabies Prevention and Control, 2007 Published April 6, 2007

http://www.cdc.gov/ncidod/dvrd/rabies/Professional/ publications/compendium/comp

Compendium of Animal Rabies Prevention and Control, 2007*

National Association of State Public Health Veterinarians, Inc. (NASPHV)

Rabies is a fatal viral zoonosis and a serious public health problem (1). The disease is an acute progressive encephalitis caused by a lyssavirus. Multiple viral variants are maintained in wild mammal populations in the United States, but all mammals are believed to be susceptible to the disease. For purposes of this document, use of the term "animal" refers to mammals.

The recommendations in this compendium serve as a basis for animal rabies-prevention and control programs throughout the United States and facilitate standardization of procedures among jurisdictions, thereby contributing to an effective national rabies-control program. This document is reviewed annually and revised as necessary. These recommendations do not supersede state and local laws or requirements. Principles of rabies prevention and control are detailed in Part I; recommendations for parenteral vaccination procedures are presented in Part II, and all animal rabies vaccines licensed by the U.S. Department of Agriculture (USDA) and marketed in the United States are listed in Part III.

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Part I: Rabies Prevention and Control

A. Principles of Rabies Prevention and Control.

- 1. **Rabies Exposure.** Rabies is transmitted only when the virus is introduced into bite wounds, open cuts in skin, or onto mucous membranes from saliva or other potentially infectious material such as neural tissue (2). Questions regarding possible exposures should be directed promptly to state or local public health authorities.
- 2. Public Health Education. Essential components of rabies prevention and control include ongoing public health education, responsible pet ownership, routine veterinary care, and professional continuing education. The majority of animal and human exposures to rabies can be prevented by raising awareness concerning rabies transmission routes; avoiding contact with wildlife; and following appropriate veterinary care. Prompt recognition and reporting of possible exposures to medical professionals and local public health authorities are critical.

- 3. **Human Rabies Prevention.** Rabies in humans can be prevented either by eliminating exposures to rabid animals or by providing exposed persons with prompt local treatment of wounds combined with the administration of human rabies immune globulin and vaccine. The rationale for recommending preexposure and postexposure rabies prophylaxis and details of their administration can be found in the current recommendations of the Advisory Committee on Immunization Practices (ACIP) (2). These recommendations, along with information concerning the current local and regional epidemiology of animal rabies and the availability of human rabies biologics, are available from state health departments.
- 4. **Domestic Animals.** Local governments should initiate and maintain effective programs to ensure vaccination of all dogs, cats, and ferrets and to remove strays and unwanted animals. Such procedures in the United States have reduced laboratory-confirmed cases of rabies in dogs from 6,949 in 1947 to 76 in 2005 (3). Because more rabies cases are reported annually involving cats (269 in 2005) than dogs, vaccination of cats should be required (3). Animal shelters and animal-control authorities should establish policies to ensure that adopted animals are vaccinated against rabies. The recommended vaccination procedures and the licensed animal vaccines are specified in Parts II and III of this compendium, respectively.
- 5. **Rabies in Vaccinated Animals.** Rabies is rare in vaccinated animals (4). If such an event is suspected, it should be reported to state public health officials; the vaccine manufacturer; and USDA, Animal and Plant Health Inspection Service, Center for Veterinary Biologics (Internet: http://www.aphis.usda.gov/vs/cvb/html/adverseeventreport.html; telephone: 800-752-6255; or e-mail: CVB@usda.gov). The laboratory diagnosis should be confirmed, and the virus should be characterized by a rabies reference laboratory. A thorough epidemiologic investigation should be conducted.
- 6. **Rabies in Wildlife.** The control of rabies among wildlife reservoirs is difficult (5). Vaccination of free-ranging wildlife or selective population reduction might be useful in certain situations, but the success of such procedures depends on the circumstances surrounding each rabies outbreak (see Part I.C.). Because of the risk of rabies in wild animals (especially raccoons, skunks, coyotes, foxes, and bats), AVMA, CSTE, NACA, and NASPHV strongly recommend the enactment and enforcement of state laws prohibiting their importation, distribution, and translocation.
- 7. **Rabies Surveillance.** Laboratory-based rabies surveillance and variant typing are essential components of rabies-prevention and -control programs. Accurate and timely information is necessary to guide human postexposure prophylaxis decisions, determine the management of potentially exposed animals, aid in emerging pathogen discovery, describe the epidemiology of the disease, and assess the need for and effectiveness of vaccination programs for wildlife.
- 8. **Rabies Diagnosis.** Rabies testing should be performed in accordance with the established national standardized protocol for rabies testing (http://www.cdc.gov/ncidod/dvrd/rabies/Professional/publications/DFA_diagnosis/DFA_protocol-b.htm) by a qualified laboratory that has been designated by the local or state health department (6,7). Euthanasia should be accomplished in such a way as to maintain the integrity of the brain so that the laboratory can recognize the anatomical parts (8). Except in the case of very small animals, such as bats, only the head or brain (including brain stem) should be submitted to the laboratory. To facilitate laboratory processing and prevent a delay in testing, any animal or animal specimen being submitted for testing should preferably be stored and shipped under refrigeration and not be frozen. Chemical fixation of

tissues should be avoided to prevent substantial testing delays and because it might preclude reliable testing. Questions regarding testing of fixed tissues should be directed to the local rabies laboratory or public health department.

9. **Rabies Serology.** Certain "rabies-free" jurisdictions might require evidence of vaccination and rabies virus antibodies for animal importation purposes. Rabies virus antibody titers are indicative of a response to vaccine or infection. Titers do not directly correlate with protection because other immunologic factors also play a role in preventing rabies, and the ability to measure and interpret those other factors are not well developed. Therefore, evidence of circulating rabies virus antibodies should not be used as a substitute for current vaccination in managing rabies exposures or determining the need for booster vaccinations in animals (9--11).

B. Prevention and Control Methods in Domestic and Confined Animals.

1. **Preexposure Vaccination and Management.** Parenteral animal rabies vaccines should be administered only by or under the direct supervision of a veterinarian. Rabies vaccinations also may be administered under the supervision of a veterinarian to animals held in animal-control shelters before release. Any veterinarian signing a rabies certificate must ensure that the person administering vaccine is identified on the certificate and is appropriately trained in vaccine storage, handling, administration, and in the management of adverse events. This practice ensures that a qualified and responsible person can be held accountable for properly vaccinating the animal.

Within 28 days after initial vaccination, a peak rabies virus antibody titer is reached, and the animal can be considered immunized. An animal is considered currently vaccinated and immunized if the initial vaccination was administered at least 28 days previously or booster vaccinations have been administered in accordance with this compendium.

Regardless of the age of the animal at initial vaccination, a booster vaccination should be administered 1 year later (see Parts II and III for vaccines and procedures). No laboratory or epidemiologic data exist to support the annual or biennial administration of 3- or 4-year vaccines following the initial series. Because a rapid anamnestic response is expected, an animal is considered currently vaccinated immediately after a booster vaccination.

- **a. Dogs, Cats, and Ferrets.** All dogs, cats, and ferrets should be vaccinated and revaccinated against rabies in accordance with Part III of this compendium. If a previously vaccinated animal is overdue for a booster, it should be revaccinated. Immediately following the booster, the animal is considered currently vaccinated and should be placed on a vaccination schedule according to the labeled duration of the vaccine used.
- **b. Livestock.** Consideration should be given to vaccinating livestock that are particularly valuable. Animals that have frequent contact with humans (e.g., in petting zoos, fairs, and other public exhibitions) and horses traveling interstate should be currently vaccinated against rabies (12,13).

c. Confined Animals.

- **1.) Wild.** No parenteral rabies vaccines are licensed for use in wild animals or hybrids (i.e., the offspring of wild animals crossbred to domestic animals). The AVMA has recommended that wild animals or hybrids should not be kept as pets (14--17).
- **2.) Maintained in Exhibits and in Zoological Parks.** Captive mammals that are not completely excluded from all contact with rabies vectors can become infected. Moreover, wild animals might be incubating rabies when initially captured; therefore, wild-caught animals susceptible to rabies should be quarantined for a minimum of 6 months. Employees who work with animals at exhibits and in zoological parks should receive preexposure rabies vaccination. The use of pre- or postexposure rabies vaccinations for handlers who work with animals at such facilities might reduce the need for euthanasia of captive animals that expose handlers. Carnivores and bats should be housed in a manner that precludes direct contact with the public (12).
 - 2. **Stray Animals.** Stray dogs, cats, and ferrets should be removed from the community. Local health departments and animal-control officials can enforce the removal of strays more effectively if owned animals have identification and are confined or kept on leash. Strays should be impounded for at least 3 business days to determine if human exposure to rabies has occurred and to give owners sufficient time to reclaim animals.
 - 3. Importation and Interstate Movement of Animals.
- **a. International.** CDC regulates the importation of dogs and cats into the United States. Importers of dogs must comply with rabies vaccination requirements (42 CFR, Part 71.51[c] [http://www.cdc.gov/ncidod/dq/animal.htm]) and complete CDC form 75.37 (http://www.cdc.gov/ncidod/dq/pdf/animal/dog_quarantine_notice_08-04-06-cdc7537.pdf). The appropriate health official of the state of destination should be notified within 72 hours of the arrival into the jurisdiction of any imported dog required to be placed in confinement under the CDC regulation. Failure to comply with these confinement requirements should be promptly reported to the Division of Global Migration and Quarantine, CDC (telephone: 404-639-3441).

Federal regulations alone are insufficient to prevent the introduction of rabid animals into the United States (18,19). All imported dogs and cats are subject to state and local laws governing rabies and should be currently vaccinated against rabies in accordance with this compendium. Failure to comply with state or local requirements should be referred to the appropriate state or local official.

- **b. Interstate.** Before interstate movement (including commonwealths and territories), dogs, cats, ferrets, and horses should be currently vaccinated against rabies in accordance with this compendium's recommendations (see Part I.B.1.). Animals in transit should be accompanied by a valid NASPHV Form 51, Rabies Vaccination Certificate (http://www.nasphv.org). When an interstate health certificate or certificate of veterinary inspection is required, it should contain the same rabies vaccination information as Form 51.
- **c.** Areas with Dog-to-Dog Rabies Transmission. Canine rabies virus variants have been eliminated in the United States (3). Rabid dogs have been introduced into the continental United States from areas with dog-to-dog rabies transmission (18,19). This practice poses a risk for introducing canine-transmitted rabies to areas in the United States where it does not exist. The

importation of dogs for the purposes of adoption or sale from areas with dog-to-dog rabies transmission should be prohibited.

- 4. **Adjunct Procedures.** Methods or procedures that enhance rabies control include the following:
- **a. Identification.** Dogs, cats, and ferrets should be identified (e.g., by metal or plastic tags or microchips) to allow for verification of rabies vaccination status.
- **b. Licensure.** Registration or licensure of all dogs, cats, and ferrets can be used to aid in rabies control. A fee is frequently charged for such licensure, and revenues collected are used to maintain rabies- or animal-control programs. Evidence of current vaccination is an essential prerequisite to licensure.
- **c.** Canvassing. House-to-house canvassing by animal-control officials facilitates enforcement of vaccination and licensure requirements.
- **d.** Citations. Citations are legal summonses issued to owners for violations, including failure to vaccinate or license their animals. The authority for officers to issue citations should be an integral part of each animal-control program.
- **e. Animal Control.** All communities should incorporate stray animal control, leash laws, animal bite prevention, and training of personnel in their programs.
- **f. Public Education.** All communities should incorporate educational programs that cover responsible pet ownership, bite prevention, and appropriate veterinary care.
 - 5. **Postexposure Management.** This section refers to any animal exposed (see Part I.A.1.) to a confirmed or suspected rabid animal. Wild, mammalian carnivores or bats that are not available for testing should be regarded as rabid animals.
- **a. Dogs, Cats, and Ferrets**. Unvaccinated dogs, cats, and ferrets exposed to a rabid animal should be euthanized immediately. If the owner is unwilling to have this done, the animal should be placed in strict isolation for 6 months. Rabies vaccine should be administered to the animal upon entry into isolation or 1 month before release to comply with preexposure vaccination recommendations (see Part I.B.1.a.). No USDA biologics are licensed for postexposure prophylaxis of previously unvaccinated domestic animals, and evidence exists that the use of vaccine alone will not reliably prevent the disease in these animals (20). Animals with expired vaccinations need to be evaluated on a case-by-case basis. Dogs, cats, and ferrets that are currently vaccinated should be revaccinated immediately, kept under the owner's control, and observed for 45 days. Any illness in an isolated or confined animal should be reported immediately to the local health department. If signs suggestive of rabies develop, the animal should be euthanized and the head shipped for testing as described in Part I.A.8.
- **b.** Livestock. All species of livestock are susceptible to rabies; cattle and horses are the most frequently infected (3). Livestock exposed to a rabid animal and currently vaccinated with a

vaccine approved by USDA for that species should be revaccinated immediately and observed for 45 days. Unvaccinated livestock should be euthanized immediately. If the animal is not euthanized, it should be kept under close observation for 6 months. Any illness in an animal under observation should be reported immediately to the local health department. If signs suggestive of rabies develop, the animal should be euthanized and the head shipped for testing as described in Part I.A.8.

Handling and consumption of tissues from exposed animals might carry a risk for rabies transmission. The risk depends in part on the site(s) of exposure, amount of virus present, severity of wounds, and whether sufficient contaminated tissue is later excised. If an exposed animal is to be slaughtered for consumption, it should be done immediately after exposure. Barrier precautions should be used by persons handling the animal, and all tissues should be cooked thoroughly. Historically, federal guidelines for meat inspectors have required that any animal known to have been exposed to rabies within 8 months be rejected for slaughter. USDA Food and Inspection Service (FSIS) meat inspectors should be notified if such exposures occur in food animals before slaughter.

In infected animals, rabies virus might be widely distributed in tissues (21). Tissues and products from a rabid animal should not be used for human or animal consumption (22). However, pasteurization temperatures will inactivate rabies virus; therefore, drinking pasteurized milk or eating thoroughly cooked animal products does not constitute a rabies exposure.

Multiple rabid animals in a herd or herbivore-to-herbivore transmission is uncommon; therefore, restricting the rest of the herd if a single animal has been exposed to or infected by rabies is usually not necessary.

- **c. Other Animals.** Other mammals exposed to a rabid animal should be euthanized immediately. Animals maintained in USDA-licensed research facilities or accredited zoological parks should be evaluated on a case-by-case basis.
 - 6. Management of Animals that Bite Humans.
- **a. Dogs, Cats, and Ferrets.** Rabies virus might be excreted in the saliva of infected dogs, cats, and ferrets during illness and/or for only a few days before illness or death (23--25). A healthy dog, cat, or ferret that bites a person should be confined and observed daily for 10 days (26); administration of rabies vaccine to the animal is not recommended during the observation period to avoid confusing signs of rabies with possible side effects of vaccination. Animals in confinement should be evaluated by a veterinarian at the first sign of illness. Any illness in the animal should be reported immediately to the local health department. If signs suggestive of rabies develop, the animal should be euthanized and the head shipped for testing as described in Part I.A.8. Any stray or unwanted dog, cat, or ferret that bites a person may be euthanized immediately and the head submitted for rabies examination.
- **b. Other Biting Animals.** Other biting animals that might have exposed a person to rabies should be reported immediately to the local health department. Management of animals other than dogs, cats, and ferrets depends on the species, the circumstances of the bite, the epidemiology of rabies in

the area, the biting animal's history, current health status, and the animal's potential for exposure to rabies. Previous vaccination of these animals might not preclude the necessity for euthanasia and testing.

- 7. **Outbreak Prevention and Control.** The emergence of new rabies virus variants and the introduction of nonindigenous viruses pose a substantial risk to humans, domestic animals, and wildlife (27--34). In such situations, the public health response should be rapid and comprehensive and should include the following measures:
- a. Characterize the virus at a national or regional reference laboratory.
- b. Identify and control the source of the introduction.
- c. Enhance laboratory-based surveillance in wild and domestic animals.
- d. Increase animal rabies vaccination rates.
- e. Restrict the movement of animals at risk.
- f. Evaluate the need for vector population reduction.
- g. Coordinate a multi-agency response.
- h. Provide public and professional outreach and education.
 - 8. **Disaster Response.** Animals might be displaced during and after manmade or natural disasters, and they might require emergency sheltering (http://www.bt.cdc.gov/disasters/hurricanes/katrina/petshelters.asp, http://www.hsus.org/disaster, and http://www.avma.org/disaster/default.asp) (35). Animal rabies vaccination and exposure histories often are not available for displaced animals, and disaster response can create situations in which animal caretakers might lack appropriate training and previous vaccination. In such situations, the following rabies-prevention and control measures should be used to reduce the risk for rabies transmission and the need for human postexposure prophylaxis.
- a. Coordinate relief efforts of persons and organizations with the local emergency operations center before deployment.
- b. Examine each animal for signs of rabies at a triage site.
- c. Isolate animals exhibiting signs of rabies, pending evaluation by a veterinarian.
- d. Ensure that all animals have a unique identifier.
- e. Administer a rabies vaccination to all dogs, cats, and ferrets unless reliable proof of vaccination exists.

- f. Adopt minimum standards for animal caretakers that include personal protective equipment, previous rabies vaccination, and appropriate training in animal handling (see Part I.C.).
- g. Maintain documentation of animal disposition and location (e.g., returned to owner, died or euthanized, adopted, relocated to another shelter, address of new location).
- h. Provide facilities to confine and observe animals involved in exposures (see Part I.A.1.).
- i. Report human exposures to appropriate public health authorities (see Part I.B.6.).
- **C. Prevention and Control Methods Related to Wildlife.** The public should be warned not to handle or feed wild mammals. Wild mammals and hybrids that bite or otherwise expose persons, pets, or livestock should be considered for euthanasia and rabies examination. A person bitten by any wild mammal should immediately report the incident to a physician who can evaluate the need for postexposure prophylaxis (2).

Translocation by humans of infected wildlife has contributed to the spread of rabies (<u>28</u>--32); therefore, the human translocation of known terrestrial rabies reservoir species should be prohibited. Whereas state-regulated wildlife rehabilitators and nuisance wildlife-control operators might play a role in a comprehensive rabies-control program, minimum standards for persons who handle wild mammals should include rabies vaccination, appropriate training, and continuing education.

- 1. **Carnivores.** The use of licensed oral vaccines for the mass vaccination of free-ranging wildlife should be considered in selected situations, with the approval of the state agency responsible for animal rabies control (5,36). The distribution of oral rabies vaccine should be based on scientific assessments of the target species and followed by timely and appropriate analysis of surveillance data; such results should be provided to all stakeholders. In addition, parenteral vaccination (trap-vaccinate-release) of wildlife rabies reservoirs can be integrated into coordinated oral rabies vaccination programs to enhance their effectiveness. Long-term, widespread programs for trapping or poisoning wildlife are not effective in reducing wildlife rabies reservoirs on a statewide basis. However, limited population control in high-contact areas (e.g., picnic grounds, camps, and suburban areas) might be indicated for the removal of selected high-risk species of wildlife (5). State agriculture, public health, and wildlife agencies should be consulted for planning, coordination, and evaluation of vaccination or population-reduction programs.
- 2. **Bats.** Since the 1950s, indigenous rabid bats have been reported from every state except Hawaii and have caused rabies in at least 40 humans in the United States (37--42). Bats should be excluded from houses, public buildings, and adjacent structures to prevent direct association with humans (43,44). Such structures should then be made bat-proof by sealing entrances used by bats. Controlling rabies in bats through programs designed to reduce bat populations is neither feasible nor desirable.

Part II: Recommendations for Parenteral Rabies Vaccination Procedures

A. Vaccine Administration. All animal rabies vaccines should be restricted to use by or under the

direct supervision of a veterinarian (45), except as recommended in Part I.B.1. All vaccines must be administered in accordance with the specifications of the product label or package insert.

- **B. Vaccine Selections.** Part III lists all vaccines licensed by USDA and marketed in the United States at the time of publication. New vaccine approvals or changes in label specifications made subsequent to publication should be added to this list. Any of the listed vaccines can be used for revaccination, even if the product is not the same as previously administered. Vaccines used in state and local rabies-control programs should have at least a 3-year duration of immunity. This constitutes the most effective method of increasing the proportion of immunized dogs and cats in any population (46). No laboratory or epidemiologic data exist to support the annual or biennial administration of 3- or 4-year vaccines following the initial series.
- C. Adverse Events. Currently, no epidemiologic association exists between any licensed vaccine and adverse events, including vaccine failure (47,48). Adverse events should be reported to the vaccine manufacturer and to USDA, Animal and Plant Health Inspection Service, Center for Veterinary Biologics (Internet: http://www.aphis.usda.gov/vs/cvb/html/adverseeventreport.html; telephone: 800-752-6255; or e-mail: CVB@usda.gov).
- **D.** Wildlife and Hybrid Animal Vaccination. The safety and efficacy of parenteral rabies vaccination of wildlife and hybrids have not been established, and no rabies vaccines are licensed for these animals. Parenteral vaccination (trap-vaccinate-release) of wildlife rabies reservoirs can be integrated into coordinated oral rabies vaccination programs, as described in Part I.C.1., to enhance their effectiveness. Zoos or research institutions may establish vaccination programs to protect valuable animals, but these should not replace appropriate public health activities to protect humans (9).
- **E. Accidental Human Exposure to Vaccine.** Human exposure to parenteral animal rabies vaccines listed in Part III does not constitute a risk for rabies virus infection. Human exposure to vaccinia-vectored oral rabies vaccines should be reported to state health officials (49).
- **F. Rabies Certificate.** All agencies and veterinarians should use NASPHV Form 51 (revised 2007), Rabies Vaccination Certificate, or an equivalent, which can be obtained from vaccine manufacturers, NASPHV (http://www.nasphv.org), or CDC (http://www.cdc.gov/ncidod/dvrd/rabies/professional/professi.htm). The form must be completed in full and signed by the administering or supervising veterinarian. Computer-generated forms containing the same information are acceptable.

Part III: Rabies vaccines licensed and marketed in the United States, 2007

Product name	Produced by	Marketed by	For use in	(mL)	Age at primary vaccination*	Booster recommended	Route of inoculation
A) MONOVALENT (Inactivated)							
DEFENSOR 1	Pfizer, Inc.	Pfizer, Inc.	Dogs	1	3 mos†	Annually	IM9 or SC1
	License No. 189		Cats	1	3 mos	Annually	SO
DEFENSOR 3	Pfizer, Inc.	Pfizer, Inc.	Dogs	1	3 mos	1 year later and triennially	IM or
	License No. 189		Cats	1	3 mos	1 year later and triennially	SC
			Sheep	2	3 mos	Annually	IM
			Cattle	3	3 mos	Annually	IM
RABDOMUN	Pfizer, Inc.	Schering-Plough	Dogs	1	3 mos	1 year later and triennially	IM or
	License No. 189		Cats	1	3 mos	1 year later and triennially	SO
			Sheep	2	3 mos	Annually	IM
			Cattle	3	3 mos	Annually	IM
RABDOMUN 1	Pfizer, Inc.	Schering-Plough	Dogs	1	3 mos	Annually	IM or
	License No. 189		Cats	1	3 mos	Annually	SC
RABVAC 1	Fort Dodge Animal Health	Fort Dodge Animal Health	Dogs	1	3 mos	Annually	IM or
	License No. 112		Cats	1	3 mos	Annually	IM
RABVAC 3	Fort Dodge Animal Health	Fort Dodge Animal Health	Dogs	1	3 mos	1 year later and triennially	IM or
	License No. 112	-	Cats	1	3 mos	1 year later and triennially	IM or
			Horses	2	3 mos	Annually	IM
RABVAC 3 TF	Fort Dodge Animal Health	Fort Dodge Animal Health	Dogs	1	3 mos	1 year later and triennially	IM or
	License No. 112		Cats	1	3 mos	1 year later and triennially	IM or
			Horses	2	3 mos	Annually	IM
PRORAB-1	Intervet, Inc.	Intervet, Inc.	Dogs	1	3 mos	Annually	IM or
	License No. 286		Cats	1	3 mos	Annually	IM or
			Sheep	2	3 mos	Annually	IM
CONTINUUM RABIES	Intervet, Inc.	Intervet, Inc.	Dogs	1	3 mos	1 year later and triennially	SC
	License No. 286		Cats	1	3 mos	1 year later and quadrennially	SC
IMRAB 3	Merial, Inc.	Merial, Inc.	Dogs	1	3 mos	1 year later and triennially	IM or
	License No. 298		Cats	1	3 mos	1 year later and triennially	IM or
			Sheep	2	3 mos	1 year later and triennially	IM or
			Cattle	2	3 mos	Annually	IM or
			Horses	2	3 mos	Annually	IM or
			Ferrets	1	3 mos	Annually	SC
IMRAB 3 TF	Merial, Inc.	Merial, Inc.	Dogs	1	3 mos	1 year later and triennially	IM or
	License No. 298		Cats	1	3 mos	1 year	IM or
	202.02.110.200		Ferrets	1	3 mos	Annually	SC
IMRAB Large Animal	Merial, Inc.	Merial, Inc.	Cattle	2	3 mos	Annually	IM or
	License No. 298		Horses	2	3 mos	Annually	IM or
	Edelide IVO. EDO		Sheep	2	3 mos	1 year later and triennially	SC
IMRAB 1	Merial, Inc.	Merial, Inc.	Dogs	1	3 mos	Annually	so
	License No. 298	mental, ma	Cats	1	3 mos	Annually	SC
IMRAB 1 TF	Merial, Inc.	Merial, Inc.	Dogs	- 1	3 mos	Annually	SC
IMPAD I II	License No. 298	mena, mo.	Cats	- 1	3 mos	Annually	so
B) MONOVALENT (Rabies glyco		otor)	00.0		0 11100	randely	-
				1	8 wks		
PUREVAX Feline Rabies	Merial, Inc.	Merial, Inc.	Cats	1	S WKS	Annually	SG
	License No. 298						
C) COMBINATION (Inactivated r	abies)						
Equine POTOMAVAC + IMRAB	Merial, Inc.	Merial, Inc.	Horses	1	3 mos	Annually	IM
	License No. 298						
CONTINUUM DAP-R	Intervet, Inc.	Intervet, Inc.	Dogs	1	3 mos	1 year later and triennially	50
	License No. 286						
CONTINUUM Feline HCP-R	Intervet, Inc.	Intervet, Inc.	Cats	1	3 mos	1 year later and	SC
	License No. 286					quadrennially**	
D) COMBINATION (Rabies glyce	oprotein, live canary pox vec	etor)					
PUREVAX Feline 3/Rables	Merial, Inc.	Merial, Inc.	Cats	1	8 wks	Annually	so
	License No. 298			-			
PUREVAX Feline 4/Rabies	Merial, Inc.	Merial, Inc.	Cats	1	8 wks	Annually	sc
Terror	License No. 298						
E) ORAL (Rabies glycoprotein,		TRICTED TO USE IN STATE	AND FED	EDAL DAS	RIES-CONTROL	PROGRAMS	
RABORAL V-RG	Merial, Inc.	Merial, Inc.	Raccoons		N/A	As determined by local	Oral
ANDONNE Y-NG	License No. 298	reneral, title.		PERM.	2005		Sidi
	License No. 298		Coyotes			authorities	

^{*} Minimum age (or older) and revaccinated 1 year later.

† One month = 28 days.

Rabies vaccine manufacturer contact information

Phone number 800-533-8536 8	Intervet, Inc.	Merial, Inc.	Pfizer, Inc.	Schering-Plough Corp.
	800-835-0541	888-637-4251	800-366-5288	800-521-5767
	http://www.intervetusa.com	http://us.merial.com	http://www.pfizerah.com	http://www.spah.com/usa

Note: ADVERSE EVENTS: Adverse events should be reported to the vaccine manufacturer and to the U.S. Department of Agriculture, Animal and Plant Health Inspection Service, Center for Veterinary Biologics (Internet: http://www.aphis.usda.gov/vs/ovb/htmi/adverseeventreport.html; telephone: 800-752-6255; or e-mail: CVB@usda.gov/.

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f Intramuscularly.

Subcutaneously.

**Non-rables fractions have a 3-year duration (see label).

^{††} Not applicable.

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